40 CFR part 61
National Emission Standards
for Hazardous Air Pollutants

EPA 402-R-96-021

NESHAPS RULEMAKING ON NUCLEAR REGULATORY COMMISSION AND AGREEMENT STATE LICENSEES OTHER THAN NUCLEAR POWER REACTORS

BACKGROUND INFORMATION DOCUMENT

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U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, DC 20460

PREFACE

The Environmental Protection Agency (EPA) is rescinding 40 CFR 61, Subpart I, National Emission Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H as it applies to licenses other than commercial nuclear power reactors. This Background Information Document (BID) has been prepared in support of rulemaking proceedings for EPA's action. This BID contains an introduction, descriptions of Nuclear Regulatory Commission (NRC) source subcategories, estimates of doses from both designated and randomly selected NRC facilities, a comparison of NRC and EPA regulations governing emissions of radioactive material, estimates of the number of NRC facilities that are in compliance with Subpart I, and a description of quality control measures used in this BID.

Copies of this BID, in whole or in part, are available to all interested persons. An announcement of the availability appears in the *Federal Register*. For additional information, contact Julie Rosenberg at (202) 233-9154 or write to:

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1. Introduction and Summary

1.1 HISTORY OF STANDARDS DEVELOPMENT

Pursuant to the 1977 amendments to the Clean Air Act (CAA), on December 27, 1979, the administrator listed radionuclides as a hazardous air pollutant under Section 112 of the Act (44 *FR* 76738). The Administrator then initiated studies to determine what source categories of facilities emit radionuclides to the air in quantities sufficient to warrant establishing a NESHAP (National Emission Standard for Hazardous Air Pollutants) to limit emissions to levels providing an ample margin of safety to protect the public health.

On April 6, 1983, EPA published a *FR* notice proposing radionuclide NESHAPs for four source categories and announced its finding that NESHAPs were not required for seven of the source categories that it had investigated (48 *FR* 15076). NESHAPs were proposed to limit emissions of radionuclides from elemental phosphorus plants, Department of Energy (DOE) facilities, certain non-fuel cycle facilities licensed by NRC, and underground uranium mines. Uranium fuel cycle facilities were one of the seven source categories that the Administrator determined did not require a NESHAP.

In October 1984, acting pursuant to a court order to take final action on the proposed NESHAPs, the Administrator published a *FR* notice announcing that the proposed standards for elemental phosphorus plants, DOE facilities, and certain NRC-licensed facilities were being withdrawn (49 *FR* 43906). The decision to withdraw the proposed standards was based on the Administrator's finding that control practices already in effect for those source categories provide an ample margin of safety. The *FR* notice also made final the Administrator's decision not to issue NESHAPs for the other seven source categories.

The decision to withdraw the proposed NESHAPs was immediately challenged in court, and on December 11, 1984, the U.S. District Court for the Northern District of California found the Administrator in contempt of its earlier order directing the Administrator to promulgate final standards or to make a finding that radionuclides are not a hazardous air pollutant. EPA complied with the court's December decision by issuing NESHAPs for elemental phosphorus plants, DOE facilities, and certain NRC-licensed facilities on February 6, 1985 (50 *FR* 7280).

The Environmental Defense Fund (EDF), the Natural Resources Defense Council (NRDC), and the Sierra Club filed petitions with the court to review the final decisions not to regulate certain source categories (including the uranium fuel cycle) and the February 1985 standards. On July 28, 1987, while these petitions were pending, the U.S. Court of Appeals for the District of Columbia remanded to the Agency the NESHAP for vinyl chlorides (a nonradioactive hazardous air pollutant). In that decision, the court concluded that the Agency had improperly considered cost and technological feasibility in determining the level of the standard without first making a determination based exclusively on the risk to the public.

Given the court's decision on vinyl chloride, EPA determined that its radionuclide NESHAPs should also be reconsidered and petitioned the court for a voluntary remand of standards. In its petition, EPA also moved that the pending litigation on all issues relating to its radionuclide NESHAPs be placed in abeyance during the rulemaking and agreed to reexamine all issues raised by the parties to the litigation. The court granted EPA's petition on December 8, 1987, and EPA began to revisit its earlier decision under a court-imposed schedule.

The Administrator's final decisions on the radionuclide NESHAPs were published in the *Federal Register* on December 15, 1989 (54 *FR* 51654). The final NESHAP for the NRC-licensed facilities (40 CFR 61, Subpart I) included facilities that are part of the uranium fuel cycle and established a standard of 10 mrem/yr effective dose equivalent (ede) to any member of the public, with no more than 3 mrem/yr ede caused by emissions of radioiodines. In explaining his decision to promulgate a NESHAP that included the uranium fuel cycle facilities previously unregulated under the CAA, the Administrator explained that the standard would insure that the current levels of emissions do not increase.

Simultaneously with promulgating the NESHAPs, EPA granted reconsideration of 40 CFR Part 61, Subpart I, National Emissions Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H. The reason for the reconsideration was to allow assessment of information received late in the rulemaking process from NRC and the National Institutes of Health (NIH) regarding the impacts of duplicative regulations on licensees and the potential

for the NESHAP to discourage the use of radioisotopes in medical and experimental therapies. The Agency also stayed the effective date of Subpart I. Over the next year, EPA continued to stay Subpart I in its entirety.

While Subpart I was under reconsideration, Congress passed the Clean Air Act Amendments (CAAA) of 1990. Section 112(d)(9) of these amendments states, in part:

> No standard for radionuclide emissions from any category or subcategory of facilities licensed by the Nuclear Regulatory Commission (or an Agreement State) is required to be promulgated under this section if the Administrator determines, by rule, and after consultation with the Nuclear Regulatory Commission, that the regulatory program established by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act for such category or subcategory provides an ample margin of safety to protect the public health.

EPA reviewed the information provided to it during the reconsideration of Subpart I concerning radionuclide emissions from one subcategory of NRC-licensed facilities, commercial nuclear power reactors. In light of the new authority provided by CAAA Section 112(d)(9), EPA made an initial determination that the NRC's regulatory program limiting these emissions protects public health with an ample margin of safety. On March 13, 1991, EPA issued an Advance Notice of Proposed Rulemaking (ANPR), announcing its intention to proceed with the rulemaking, pursuant to Section 112(d)(9), to rescind Subpart I of 40 CFR 61, as it applies to nuclear power reactors (56 *FR* 10524). Concurrent with the ANPR, EPA published a *FR* notice proposing to stay the effectiveness of Subpart I for power reactors until the conclusion of the rulemaking on recision (56 *FR* 10523). On August 5, 1991, EPA issued a Notice of Proposed Rulemaking (NPR) announcing the Agency's intention to rescind Subpart I as it applies to nuclear power reactors (56 FR 37196). At the same time, EPA stayed subpart I for these facilities pending completion of the recision rulemaking.

For all other categories of NRC licensees, EPA concluded that it lacked adequate information to characterize the facilities' emissions and embarked on the information collection survey (under Section 114) that is described in detail in this Background Information Document (BID). On April 15, 1991, EPA stayed the effectiveness of Subpart I for all NRC-licensed facilities other than nuclear power reactors until November 15, 1992, or until such earlier date that EPA is prepared to make an initial determination under CAAA Section 112(d)(9) and conclude its reconsideration (56 FR 18735, April 24, 1991). On

December 1, 1992, the Administrator determined that the NRC regulatory program for licensed facilities other than commercial nuclear reactors should provide an ample margin of safety to protect public health, and proposed to rescind Subpart I as it applies to such licensees.

1.2 UPDATE METHODOLOGY

In previous evaluations (EPA83, EPA84, EPA89), EPA used both actual and model facilities to characterize the doses and risks caused by airborne emissions of radionuclides from NRC-licensed facilities. In those assessments, the doses caused by activities judged to have the greatest potential for relatively large airborne emissions were evaluated primarily on the basis of actual facilities. Most of these large facilities had emissions data providing a basis for reasonable estimates of doses and risks to public health. Emissions from model facilities were used in an attempt to bound the doses and risks from the thousands of facilities engaged in activities judged to have less potential to cause exposures. These estimates were based on available data and conservative assumptions to ensure that doses and risks were not understated.

The most recent evaluation of emissions from NRC-licensed facilities, conducted for the 1989 promulgation of the Subpart I NESHAP, used the methodology that EPA developed to meet the approach that the U.S. Court of Appeals for the D.C. Circuit set out in the *Vinyl Chloride* decision. That approach requires two steps in setting standards: first, determine an "acceptable" level of risk that considers only health factors, and second, set a standard that provides an "ample margin of safety," in which cost, feasibility, and other relevant factors in addition to health may be considered. The Agency's methodology utalizes a multifactor approach which focuses on three measures of risk:

- Maximum Individual Risk (MIR) - an estimate of the risk incurred by the individuals most exposed to the effluent from a given facility. For radionuclide NESHAPs, EPA estimated the lifetime fatal cancer risk that would result from continuous exposure over the individual's entire lifetime. A lifetime MIR of approximately 1 in 10,000 (1E-04) is judged to be presumptively acceptable.

- Incidence - an estimate of the total number of health effects in the population residing within 80 kilometers of the facilities in the source category. Incidence is considered with other health risk information in judging acceptability.

- Risk Distribution - an estimate of the number of persons at a given level of MIR and the estimated fraction of the total number of health effects expected to be incurred in the population within each range of risks. As a goal, EPA seeks to assure that as many individuals as possible are at an MIR of 1 in 1 million (1E-06) or less.

Using these criteria, EPA found that the risk from all actual facilities evaluated (both NRC-licensed facilities covered under Subpart I and uranium fuel cycle facilities that were not at that time covered by a NESHAP) were acceptable. The evaluations based on conservatively modeled facilities also met these criteria. While the highest doses estimated for any actual facility in those assessments were within the range that the Administrator has determined to be safe, the total number of facilities and the diversity of the activities in which they are engaged resulted in some uncertainty that the facilities causing the highest individual doses had actually been identified and evaluated.

To provide the Administrator with enough information to determine whether the NRC's regulatory program protects public health with an ample margin of safety, the Agency has performed additional dose estimates to provide a "snapshot" of current emissions and doses. EPA has also analyzed the NRC's regulatory program to determine if the program can ensure that future emissions provide for the public health with an ample margin of safety.

For the large facilities previously evaluated by EPA, updated emissions, meteorological, and population information was obtained and new dose estimates made to better account for previous limitations. Dose estimates were also performed for facilities that had not been studied earlier but where concerns remained that radioactive emissions could present significant risks. These analyses are called the Designated Survey.

For a more accurate characterization of the doses attributable to the many smaller licensees that previously had been evaluated by using model facilities, EPA has taken a statistical approach, based on a random sample of a subset of NRC and Agreement State licensees. Facilities that had already been evaluated by EPA and facilities that are only licensed to use sealed sources of radioactive materials were excluded from the subset of

licensees to be surveyed. The random sample of licensees was selected from lists provided by NRC and the Agreement States. As these lists included some facilities licensed to use only sealed sources, over-sampling was employed and all selected facilities that only use sealed sources were excluded from the analysis. From this random sample, information from 367 users of radioactive material was evaluated. The data needed to evaluate doses were obtained by a survey form mailed to each randomly chosen facility, and doses were estimated using the COMPLY computer code. These analyses are called the Random Survey.

1.3 PURPOSE OF THIS BACKGROUND INFORMATION DOCUMENT

This BID provides background information from the Designated and Random Surveys to assist the Administrator in determining whether the NRC's regulatory program maintains radioactive emissions sufficiently low to protect the public health with an ample margin of safety. This BID also includes a comparison of NRC and EPA regulations governing airborne radioactive emissions and a detailed description of the Agency's procedures and methods for estimating radiation dose due to radioactive emissions to the air. This material is presented as follows:

- Chapter 2 - A description of the EPA regulations that limit the effective dose equivalent to members of the general public and the method for determining compliance with that dose limit. This chapter also summarizes the organizational and administrative controls imposed by NRC on materials licensees.

- Chapter 3 - A description of the annual doses resulting from emissions from designated NRC licensees (the Designated Survey). This chapter also provides the reasons for the selection of the designated facilities.

- Chapter 4 - A description of the annual doses resulting from emissions from randomly selected NRC licensees (the Random Survey). This chapter also describes the methods for ensuring the selection of a statistically significant random sample, data requirements for performing realistic dose estimates, and the statistical methods used to evaluate the raw data.

- Chapter 5 - A description of the quality control measures instituted to ensure a high level of confidence in the results of the BID.

This BID also contains several appendices. Appendix A describes the organization of NRC and its regulations. Appendix B describes various NRC Regulatory Guides pertinent to

radioactive emissions and exposure control. Appendix C describes the various licensee activities for which an NRC or Agreement State license is required. Appendix D identifies the types of facilities selected for the Random Survey. Appendix E describes quality assurance requirements for nuclear power plants and fuel reprocessing plants. Appendix F lists the NRC Agreement States and contact persons. Appendix G contains a copy of the questionnaire sent to the randomly selected facilities to obtain site-specific information. Appendix H discusses the assumptions used in the dose calculations performed.

1.4 SUMMARY

The major findings of this BID for NRC-licensed facilities other than nuclear power reactors include:

1. The highest dose found in the Random Survey was 8 mrem/yr from all radionuclides and 0.7 mrem/yr from radioiodines. The highest dose found in the Designated Survey was 8 mrem/yr from all nuclides and 1 mrem/yr from radioiodines. This indicates that, in general, the doses being received by the members of the public at greatest risk are lower than the NESHAP standard established by the Administrator (10 mrem/yr ede with not more than 3 mrem/yr ede caused by radioiodines).

2. Because the doses received by members of the public vary from year to year for any given facility, a trend for all facilities could not be established from the available data. However, NRC regulatory requirements have become more stringent over time, and it may be inferred that this will result in a downward trend in future airborne releases.

3. NRC begins to consider doses received by the public from radioactive effluents at the time of license application and continues to evaluate the potential for effluents to cause doses in excess of regulatory limits throughout a facility's lifetime. The stringency of NRC's requirements varies with the potential of licensed facilities to place the health and safety of the public at risk. However, all facilities must comply with the limits established in 10 CFR Part 20, Standards for Protection Against Radiation, and fuel cycle facilities must also meet the requirements of 40 CFR 190, Environmental Radiation Protection Standards for Nuclear Power Operations.

4. NRC has recently amended the requirements in 10 CFR Part 20. The amendments, consistent with Federal guidance and the International Commission on Radiological Protection (ICRP), establish a risk-based system of dose limitations. For members of the general public, the amendments lower the maximum permissible dose to 100 mrem/yr total effective dose equivalent (tede) from direct radiation and exposure to gaseous and liquid effluents. The derived air concentrations (DACs) that may be used to demonstrate compliance with the 100 mrem/yr tede limit are based on 50 mrem/yr tede to account for multiple pathways.

5. The Part 20 amendments also establish the requirement, previously just guidance, that all licensees conduct operations in a manner such that doses to both workers and members of the public are as low as is reasonably achievable (ALARA).[1] Revised Part 20, although still allowing a higher maximum permissible dose than the NESHAP, is more restrictive than the regulations that have resulted heretofore in actual doses to members of the public below the NESHAP limits. For this reason, the NRC program should result in future emission levels no higher than current emissions levels.

Based on the results obtained from the Random Survey of NRC-licensed facilities, the vast majority of facilities (over 99.5 percent) are not causing doses greater than the NESHAP standards of 10 mrem/yr ede from all radionuclides with not more than 3 mrem/yr ede from radioiodines. In fact, the majority (>95 percent) have emissions that result in doses of less than 1 mrem/yr ede. Based on statistical considerations, EPA expects that 14 facilities out of approximately 6,000 may cause doses in excess of the NESHAP standard.

Estimated doses from the Designated Survey and the Random Survey are summarized in Table 1-1.

[1] Per 10 CFR 20, ALARA is an acronym for "as low as is reasonably achievable" and means making every reasonable effort to maintain exposures to radiation as far below the dose limits in 10 CFR Part 20 as is practical, consistent with the purpose for which the licensed activity is undertaken. The requirement takes into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and the value of utilizing nuclear energy and licensed materials in the public interest.

Table 1-1. Summary of estimated doses.

Survey	Licensee Category		Maximum Estimated Dose mrem/yr ede	Maximum Estimated Iodine Dose mrem/yr ede
Designated Survey	U-Fuel Cycle	U-Mills & Tailings	2	N/A
		UF_6 Conversion (Wet Cycle)	7	N/A
		Fuel Fabrication	6E-02	N/A
	Test and Research Reactors		4	N/A
	Radiopharmaceutical Manufacturers		5	2E-01
	Hospitals and Medical Research Facilities		8	1
	Manufacturers of Sealed Sources		4	N/A
	Depleted Uranium Munitions		6E-04	N/A
	Rare Earth Processors		2	N/A
	Commercial Low-Level Radioactive Waste Disposal and Incineration[1]		7E-01	7E-01
Random Survey[2]			8	7E-01

1. This value is estimated for a facility not yet designed or built. The highest dose from an operating facility was 7E-03 mrem/yr.

2. With 95 percent assurance, the 99.6th percentile of the distribution of doses from these facilities does not exceed 8 mrem/yr, where 8 mrem/yr ede is the highest dose estimated for all the facilities in the sample. Radioiodines contributed a very small fraction to the effective dose equivalent of the maximally exposed individuals.

2. Description of Regulatory Programs

This chapter briefly summarizes the organizational and administrative controls imposed by EPA and NRC on licensees for establishing emissions controls and for assuring that emissions are not likely to increase in the future. A much more detailed description of the NRC program can be found in Appendix A, and supplementary information is contained in Appendices B, C, and E.

2.1 THE EPA'S REGULATORY PROGRAM UNDER THE CLEAN AIR ACT

2.1.1 Requirements

EPA regulations limit the effective dose equivalent (ede) to any member of the public to 10 mrem/yr from all airborne radionuclides with no more than 3 mrem/yr from radioiodine. EPA does not license facilities; instead, each facility is required to prepare an annual report evaluating the doses from its emissions to the most exposed member of the public. To minimize the burden on small users of radioisotopes, EPA does not require the report to be filed with EPA if the estimated dose is less than 10 percent of the standard.

EPA has provided a number of methods for the user to demonstrate compliance with the standard. They range from very simple to fairly complicated. They are all based upon the methods developed by the National Council on Radiation Protection and Measurements (NCRP).

2.1.2 Methods for Demonstrating Compliance

In 1986, the NCRP published Commentary No. 3, "Screening Techniques for Determining Compliance with Environmental Standards," in response to a need indicated by EPA for simple methods to assess compliance with the NESHAPs (NCRP86). Commentary No. 3 was revised in January 1989. EPA-approved methods for demonstrating compliance with the NESHAPs are all based upon the January 1989 revision. In addition, EPA allows the use of other methods for demonstrating compliance, provided they have been approved by the Agency.

The EPA-approved methods form a tiered set of procedures, ranging from very simple to moderately complex. They are intended to suit the needs of all types of facilities, ranging from those with simple operations involving only small amounts of radioactivity to those having complex operations involving large amounts of radioactivity.

The simplest procedures can be carried out using only a hand calculator; the most complicated one requires a computer. All of the procedures have been put into the computer program COMPLY, which is available from EPA. COMPLY has been designed to be user-friendly and even at the highest level (the most complex method) requires a minimum amount of input.

If the licensee is unable to demonstrate compliance using one of the simpler procedures, the licensee is allowed to go to a more complicated one. If the licensee cannot demonstrate compliance at the highest level, the licensee must report that fact to EPA. Facilities in compliance must file an annual report with EPA unless their estimated doses are less than 10 percent of the limits. The EPA-approved compliance procedures are as follows:

- Level 1 - Possession Tables. This is the simplest method and is intended for use by licensees who do not monitor their emissions. The licensee computes the ratio of the annual amount of each radionuclide used to a standard value for the radionuclide. The licensee then sums these ratios, and if the sum is less than one, compliance with the dose standard is demonstrated.

- Level 1 - Concentration Tables. This simple method can be used by licensees who measure their stack concentrations. The licensee computes the ratio of the measured stack concentration of each radionuclide to a standard value for that radionuclide. Compliance with the dose standard is demonstrated if the sum of the ratios is less than one.

- Level 2. This corresponds to Screening Level 2 of NCRP Commentary No 3. It requires such information as the release rate of each radionuclide, the release height, the building dimensions, and the distance from the point of release to the nearest receptor. It may also require some information about the size of the stack or vent. If the release rates are not measured, EPA has provided simple methods to estimate them. If desired, the licensee may supply

the annual wind speed or use the default value of 2 meters/second. If the dose is less than 10 mrem/yr from all radionuclides and 3 mrem/yr from radioiodine, the licensee is in compliance with the dose standard.

- Level 3. This corresponds to Screening Level 3 of NCRP Commentary No. 3. In addition to the information needed at Level 2, it requires the user to supply the distances to the nearest farms producing vegetables, milk, and/or meat. If the dose is less than 10 mrem/yr from all radionuclides and 3 mrem/yr from radioiodine, the licensee is in compliance with the dose standard.

- Level 4. This is the highest level. It is based upon the methods of NCRP Commentary No. 3, but with some differences, the principal one being the optional use of a wind rose. At the other levels, it is assumed that the wind blows from the source toward the receptor 25 percent of the time; if the licensee supplies a wind rose, the actual frequencies for the 16 sectors are used along with the actual wind speed in each sector. The licensee must supply distances to receptors in each of the 16 sectors. COMPLY then determines which of these receptors receives the highest dose. If the dose is less than 10 mrem/yr from all radionuclides and 3 mrem/yr from radioiodine, the licensee is in compliance with the dose standard.

Levels 1-3 are simple enough to carry out with a hand calculator; instructions are contained in EPA89a. Level 4 must be carried out using the COMPLY code on an IBM-compatible computer.

The COMPLY code considers four pathways of exposure: inhalation, ingestion, immersion, and external exposure to surface contamination. Because it accounts for building wake effects, it is suitable for close-in distances. At distances beyond the recirculation zone near a building, it uses a modified Gaussian plume model. It accounts for decay and in-growth of daughter radionuclides during transit from the release point to the receptor and the farms, after being deposited on vegetation and soil, and after harvest, milking, or slaughter. It also accounts for deposition of radioactivity upon food crops and forage and for uptake from the soil. At Levels 1-3, these processes are handled by pathway factors developed by the NCRP; at Level 4, the calculations are done explicitly.

2.2 THE NRC'S REGULATORY PROGRAM UNDER THE ATOMIC ENERGY ACT

The regulatory programs established by NRC are intended to satisfy its statutory obligations under the Atomic Energy Act of 1954, as amended, to protect the health and safety of both workers and members of the public. NRC implements its programs either directly through licensing and inspection of facilities, or through the Agreement State program, in which NRC relinquishes its regulatory authority for most facilities to the states. Agreement States perform the licensing and inspection functions.

Facilities are regulated under Chapter 1 of Title 10 of the *Code of Federal Regulations* (10 CFR) and are licensed by NRC according to the type of radioactive material that they use or possess and/or the type of activity in which they are engaged. The five major types of licenses affected by Subpart I are: Parts 30-39 Licenses for specific uses of byproduct material;[2] Part 40 Licenses for source material (unenriched uranium or thorium); Part 50 Licenses for production and utilization facilities (reactors and reprocessing plants); Part 61 Licenses for land disposal of low-level radioactive wastes; and Part 70 Licenses for special nuclear material (plutonium and enriched uranium). Licensees are subject to the specific requirements established by the CFR part under which they are licensed and the generally applicable requirements established in other parts of Chapter I of Title 10 of the *Code of Federal Regulations*, such as 10 CFR 20. The vast majority of licenses are for activities using byproduct material regulated under Parts 30-39.

The NRC's regulations limiting routine radionuclide airborne emissions are contained in 10 CFR Part 20, Standards for Protection Against Radiation, which applies to all licensees. For members of the public, the basic dose limit was recently amended to limit individual exposures to 100 mrem/yr total effective dose equivalent (tede). The 100 mrem/yr limit includes direct radiation and doses from both gaseous and liquid effluents. In addition, recent amendments to Part 20 require that all licensees implement a radiation protection

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[2] Byproduct materials are man-made radioactive materials (except special nuclear material) produced or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear materials such as in a nuclear reactor. Byproduct material does include activation products from nuclear reactors and from plutonium-beryllium (Pu-Be) neutron sources, but does not include activation products from other neutron sources such as Cf-252 or accelerators. Byproduct Material Licenses are issued to educational institutions, medical facilities, industrial facilities, and individuals for the possession and use of byproduct materials and radionuclides for teaching, training, research and development, manufacturing, equipment calibration, medical research and development, medical diagnosis and/or therapy.

program that keeps exposures as low as is reasonably achievable (ALARA). Formerly, this stated that other facilities "should" attempt to maintain exposures and effluents ALARA. The revisions to Part 20 must be implemented by all licensees prior to January 1994.

In support of the Part 20 amendments, NRC issued draft Regulatory Guide DG-8013, "ALARA Levels for Effluents from Materials Facilities," in October 1992. This document provides guidance to licensees on designing and implementing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities. The guide also states that, based on practical experience, an ALARA goal of about 10 millirem per year should be achievable by most licensees.

In addition to complying with the 10 CFR Part 20 limits, licensees must comply with license conditions, which are often tailored to individual facilities. Also, licensees that are part of the nuclear fuel cycle must comply with the EPA standard established in 40 CFR Part 190, Environmental Protection Standards for Nuclear Power Operations. Part 190 requires that the doses to real individuals from all uranium fuel cycle sources, considering all gaseous and liquid effluent pathways and direct radiation, not exceed 25 mrem/yr to the whole body or any organ except the thyroid, for which the dose limit is set at 75 mrem/yr.

The NRC's licensing program can be best understood as a "tiered" or "graduated" program based on the potential hazards associated with the types and quantities of radioactive materials used and the activities authorized. The greater the potential hazard, the more stringent the requirements. In general, the licensing procedures require the applicant for a license to:

- list the activity or activities for which a license is sought;
- identify the facility or portions of the facility where the licensed materials will be used, including a description of all engineered controls;
- identify the training and qualifications of the persons authorized to use the material, and/or of the radiation safety officer designated to oversee licensed activities;
- describe the procedural controls to be employed to assure containment and physical protection of the radioactive materials;
- establish the limiting conditions for operations; and
- implement confirmatory monitoring and/or radiation surveys.

The degree of specificity in the license application, the extent of application review, and/the extent of license conditions imposed are all related to the potential hazards associated with the activity. Fuel cycle and other "large" facilities must meet the most stringent requirements (NRC does not define "large" licensees, but in general, large licensees are those required to submit the data needed to prepare an Environmental Impact Statement or Assessment at the time of license application or renewal). Other licensees (predominately research and medical facilities holding byproduct licenses issued under Parts 30-39) must meet somewhat less detailed obligations but must still provide the basic information listed above.

In the case of these "other" licensees, where the potential for airborne releases of radioactive materials is small, continuous effluent monitoring requirements are usually not imposed, but periodic confirmatory measurements must be made. If the potential for releases is more substantial, requirements will include both stack monitoring and confirmatory environmental sampling and analysis. The recent amendments to Part 20 include requirements detailing how licensees are to demonstrate compliance with the annual dose limit. These amendments also require that all licensees retain the records needed to confirm that dose limits have not been exceeded until the license is terminated. Periodic onsite inspections are conducted to confirm that the licensee has operated the facility in full compliance with the applicable regulations and license conditions. For byproduct material licensees using non-sealed sources, inspections are conducted approximately every one to seven years, depending on the quantity of material possessed, the type of activity conducted, and the priority assigned by NRC. Priority seven licensees receive an initial inspection and are only inspected again if a particular problem arises.

2.3 COMPARISON OF THE NRC'S REQUIREMENTS WITH THE NESHAP

The NESHAP established in 40 CFR 61, Subpart I, requires NRC-licensed facilities to determine compliance with the 10 mrem/yr (no more than 3 mrem/yr from radioiodines) dose limit annually. Facilities are required to maintain records of their calculations and supporting data; if the calculated doses exceed 10 percent of the standard, they must file an annual report with EPA. Facilities seeking to build a new source must prepare and submit an application for construction approval if the estimated doses from the source equal or exceed 10 percent of the standard. Facilities seeking to modify an existing source must prepare and submit an application for construction approval if the doses from the proposed

modification are equal to or greater than 1 percent of the standard or if doses from the entire facility, including the modification, are equal to or greater than 10 percent of the standard.

Because the Designated Survey (Chapter 3) and the Random Survey (Chapter 4) evaluate facilities whose operations are restricted by the pre-existing 10 CFR 20, it is appropriate to compare the NESHAP to the pre-existing standard as well as the revised version. Table 2-1 compares the NRC's requirements for both fuel cycle and other large facilities and other licensees and the requirements of the NESHAP.

As detailed in Appendix A, the pre-revision Part 20 required large licensees to develop and report extensive data on their effluent releases and to be subject to extensive confirmatory inspections. However, of the approximately 6,000 facilities in the study population, only a tiny fraction are large licensees. In addition to 150 fuel cycle facilities, there are perhaps another 50 large materials licensees. Other NRC licensees are not required to estimate doses to members of the public, nor are they required to calculate routinely and report their compliance with the derived air concentrations (DACs), formerly called maximum permissible concentrations (MPCs), of radionuclides for unrestricted areas. However, these small licensees do develop and maintain most of the data needed to determine compliance with the limits imposed by the NESHAP and to prepare an application for approval to construct or modify.

Discussions with personnel at medical and research facilities indicate that seldom, if ever, will an applicant propose DACs greater than those established by 10 CFR Part 20.106. Thus, the DACs for unrestricted areas are the *de facto* limits for these licensees. However, because licensees typically assess these concentrations in the stack, the concentrations in open areas are lower due to dispersion.

This notwithstanding, the basic limits imposed by NRC via either the old or new Part 20 are less restrictive than those imposed by the EPA's NESHAP. Other differences between the NESHAP and the pre-existing Part 20 are primarily due to two differences in the methodologies used by NRC and EPA to estimate dose. The first is that the NRC's MPCs are based primarily on the inhalation pathway. By contrast, EPA concentrations consider doses received via the immersion, inhalation, ingestion, and ground-surface pathways. The second difference is that NRC's MPCs are based on ICRP II recommendations, and EPA's are based on ICRP 26 and 30. With the revision to Part 20, the differences between NRC and EPA are lessened since the new Part 20 uses ICRP 26 and 30 methodology.

Table 2-1. Summary of regulatory requirements.

Regulatory Activity	NRC Requirements for Large NRC Licensees	NRC Current Part 20 for Other Licensees	EPA's NESHAP	NRC Revised Part 20
Licensing or Approval	Environmental report, safety analysis report, ALARA design review, technical specifications	Facility design handling/use procedures, possession limits.	Facility design, effluent controls, quantities of material by chemical & physical form, dose estimate, but only if $\geq$ 10 percent of limits	No change.
Dose Limit	Per technical specifications. For fuel cycle facilities 25 mrem/y whole body or any organ (75 mrem/y thyroid).	Per license condition or limits in 20.105 & MPCs in 20.106	10 mrem/y, not more than 3 mrem/y due to radioiodines.	100 mrem/y total ede to any member of the public. Doses from direct radiation, liquid and gaseous effluents must be counted. Dose rate must be less than 2 mrem/hr. Licensees subject to 40 CFR 190 must comply with that standard in addition to NRC limits.
Records	Results of surveys, effluent monitoring, environmental measurements, dose calculations for 40 CFR 190 compliance.	Results of surveys, material receipts, ventilation rates.	Effluent monitoring data or annual possession of materials data used to determine compliance.	All licensees must retain records needed to demonstrate compliance with dose limits until license is terminated.
Reports	Quarterly or semi-annual source terms, and environmental monitoring results, annual dose report for 40 CFR 190 compliance.	Exposures or releases greater than 10 times 20.105 or 20.106.	Annual dose calculations if greater than 10 percent of limits.	As before, except any exceedence of dose limits must be reported within 30 days.
Inspections	Annual or resident inspectors, follow-up on previous violations.	Once, or once every 1 to 7 years, depending on type of license and activities conducted.	Under development.	No change.
Enforcement	Five violation levels based on safety implications, corrective actions, fines, orders, license revocation; citizens may petition NRC to enforce, but if the EDO does not agree, no action is taken.	Same as for large facilities.	Monthly reports for facilities not in compliance; citizens may take legal actions (CAA, Section 304) to compel compliance.	No change.

2.4 NRC-LICENSED FACILITY PROGRAM ANALYSIS

The NRC's programs for "Fuel Cycle and Other Large Facilities" provide regulations to limit airborne radionuclide emissions to the atmosphere. As described in Appendix A, the NRC's requirements for facility design, environmental impact assessment, and safety analysis (10 CFR 30, 32, 33, 35, 39, 40, 50, 70), together with a comprehensive enforcement and inspection program, provide reasonable assurance for the protection of the public.

In reviewing the regulatory program for "other facilities," several observations are notable. First, other facility licensees, although required to evaluate their compliance with the DACs established by the revised 10 CFR Part 20 (Appendix B to 10 CFR 20.1001-20.2401), need not submit their calculations to NRC for review, even at the time of initial application. Second, ALARA requirements apply to all licensees and to emissions from the facility as well as to workers. Third, with respect to releases of radioactive materials, the only reporting requirement imposed on these licensees is to notify NRC if concentrations exceed 10 times the allowable DACs.

Although the monitoring and inspection process for these facilities are relatively infrequent, NRC requires the facility to keep the concentrations of radioactive materials in effluent air at or below the levels of the DACs. The NRC or Agreement States often recommend that the license applicant use a more conservative approach in calculating potential airborne effluent concentrations released in the exhaust system or at the stack. In general, a "10 percent at the stack" rule is recommended as the starting point of the estimation (NRC84a). This approach lowers the total effective dose equivalent to individual members of the public residing close to the institution. In addition, it reduces the potential of exceeding the regulatory limits set forth in Table II of Appendix B to 10 CFR Part 20 even in the event of minor operational errors.

The airborne effluent concentrations at the release point of the emission are used to estimate the total effective dose equivalent to the public at the receptor locations which are farther away (ranging from several hundred feet to several miles). However, the estimation does not usually take into account the effluent dispersion and dilution factors in the atmosphere. These factors will make the dose lower. On the other hand, the NRC's DACs only calculate the dose from inhalation and immersion and do not take into account the dose from ingestion or ground deposition. In some cases, these may be the major pathways.

The NRC's and the Agreement States' regulatory programs control the use of radioactive byproduct material. The programs also provide a regulatory mechanism to limit airborne radionuclide emissions to the atmosphere from research and development facilities, manufacturing facilities, and medical institutions. However, because effluents are not actually measured by stack instruments, NRC must rely on the licensees' administrative programs for assurance that concentrations of radioactive materials in effluent air do not exceed the levels of the DACs.

Given the lack of monitoring requirements for these facilities, the lack of guidance on appropriate assumptions for releases of materials that are not handled as gases or aerosols, and the infrequent inspections at these facilities, EPA decided to conduct an analysis of the doses caused by these facilities to judge the adequacy of the NRC's program.

3. Results of Designated Survey of NRC-Licensed Facilities

This chapter updates the emissions and doses from a small group of actual NRC-licensed facilities (those included in the Designated Survey) that are currently subject to the Subpart I NESHAP. These facilities belong to the following source categories: uranium fuel cycle (Section 3.1), test and research reactors (Section 3.2), radiopharmaceutical and radiolabeled compound manufacturers (Section 3.3), large hospitals and medical research facilities (Section 3.4), manufacturers of sealed sources (Section 3.5), depleted uranium munitions test sites (Section 3.6), rare earth and thorium processors (Section 3.7), and commercial low-level radioactive waste disposal and incineration facilities (Section 3.8). Most of the facilities in the Designated Survey were analyzed by EPA (EPA73a, EPA73b, EPA78, EPA79, EPA82, EPA83, EPA84, EPA86, EPA89) prior to the reconsideration period. In this study, several of the source categories are evaluated in greater detail than in previous studies.

The facilities in the Designated Survey were selected based on expert opinion that they had the greatest potential for causing the highest doses. It was believed that if the evaluation of these facilities demonstrates that the public health and safety is protected with an ample margin, the same can be concluded about smaller facilities. To be certain that it has identified those facilities causing the greatest dose to a member of the general public, EPA designed and conducted the Random Survey, the results of which are presented in Chapter 4. Appendix D describes in more detail the types of facilities evaluated in the random survey.

The Designated Survey updates previous analyses to improve the accounting for (a) the wide diversity of facilities, (b) the limitations in the available database, and (c) the limitations of dispersion models for evaluating certain facilities. This analysis draws upon and updates previous evaluations and incorporates revisions to the estimates based on new information developed during the public comment period. Because this BID draws upon all past work and provides new information, it represents EPA's most recent and comprehensive analysis of the doses caused by these facilities.

Current information used in evaluating doses was obtained through research of licensee dockets contained in the NRC Public Document Room (PDR); responses to formal, written questionnaires; EPA studies conducted since EPA89 (EPA91, EPA92); and telephone

interviews with the licensees. In all cases, available facility information was reviewed to ascertain the potential for significant airborne emissions. Potential doses were evaluated for activities where potential existed for a facility to exceed the Subpart I NESHAP dose limits. The results demonstrate that all NRC licensees examined as part of the Designated Survey are currently meeting the standard. The dose estimates are summarized in Section 3.9.

For each source category, this chapter presents the results of prior studies (up through and including the 1989 NESHAP studies), studies that have been undertaken since the 1989 NESHAP studies but before this study, and the results of this study, the Designated Survey.

3.1 URANIUM FUEL CYCLE FACILITIES

Uranium fuel cycle facilities consist of: mills that extract uranium from ore and their accompanying tailings piles; conversion facilities that chemically convert uranium feed from the mills (yellowcake) to uranium hexafluoride; the enrichment plants (owned by DOE but not regulated by NRC) that enrich uranium in the uranium-235 isotope; fuel fabrication facilities that convert uranium from the hexafluoride to an oxide form, pelletize the uranium, and incorporate it into fuel rods for power reactors; pressurized-water and boiling-water power reactors; spent reactor fuel storage and disposal facilities; and, although none are currently operating or envisioned, fuel reprocessing plants that recover residual fissile material (uranium and plutonium) from spent fuel. This section presents the results of the current evaluation of airborne emissions from uranium mills, uranium hexafluoride conversion facilities, light water reactor fuel fabricators, and spent fuel storage. Dose estimates are presented for each source category analyzed and are summarized in Section 3.9. Emissions from power reactors are covered in another analysis for a separate rulemaking (EPA91).

3.1.1 Uranium Mill Tailings

Uranium mills extract uranium from ores which contain only 0.01 to 0.3 percent U_3O_8. The product of the mills is shipped to conversion plants where it is converted to volatile uranium hexafluoride (UF_6) which is used as feed to uranium enrichment plants. Emissions of radon from this process are regulated by separate NESHAP standards, Subpart T for disposal of tailings and Subpart W for operating mill tailings.

3.1.1.1 Previous Evaluations. EPA's most recent analysis (EPA89) of uranium mills focused on mills with dry tailings piles that were either operating or on standby. The study also included analysis of a generic model mill to assess the dose and risk from tailings piles at mills that are either decommissioned or undergoing decommissioning. The maximum dose calculated for an operating mill was for the Homestake Mill. The dose from process exhaust was 12.8 mrem/yr ede and the dose from the tailings pile was 0.95 mrem/yr ede.[3] The dose obtained for the model mill's tailings pile was 25.8 mrem/yr effective dose equivalent (ede).

3.1.1.2 Evaluations of Specific Facilities Made During the Reconsideration Period. Since the dose reported in EPA89 for the model mill's tailings exceeded the Subpart I NESHAP dose limits and since the schedule for remediation of mill sites may change, EPA decided to look at all mills with exposed piles. EPA, NRC, and affected Agreement States have entered into a Memorandum of Understanding (MOU) (56 FR 67564) addressing the schedule for remediation of non-operational tailings piles. The objective of the MOU is to assure the installation of an earthen cover at all current disposal sites by the end of 1997, or within 7 years of when the existing operating and standby sites enter disposal status.

Doses from mill process exhausts have not been re-evaluated because Homestake Mill has ceased operations, and the dose from all other operating mills evaluated in EPA89 were all less than 0.3 mrem/yr ede which is below the Subpart I NESHAP dose limit.

Table 3-1 lists all NRC-licensed mill sites that currently have exposed tailings. This evaluation utilizes the most recent information on dry tailings areas and radium-226 concentrations. These data were obtained from the NRC Public Document Room, from NRC's Uranium Recovery Field Office, and from conversations with cognizant personnel in EPA's Regions 6 (Phil Shaver), 8 (Ed Kray), and 10 (Leo Wainehouse) between July and August 1991. Demographic and meteorological data were taken from EPA89. Based on the demographic data, assumptions were made concerning the placement of farms. These assumptions are consistent with those made in the Random Survey portion of the study.

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[3] The dose of 12.8 mrem/yr was estimated prior to Homestake's commitment to install yellowcake drying and packaging scrubbers. Given a decontamination factor of 10 for scrubbers, the prospects were good for future emissions to be below the NESHAP limit of 10 mrem/yr. Homestake has since ceased operations and is being decommissioned.

Table 3-1. COMPLY code input data for uranium mills.

State/Mill	Owner	Met Tower Location	Dry Surface Area[1,2] (m^2)	Distance to Nearest Resident[2] (m)	Ra-226 Conc.[2] (pCi/g)	Calculated Release Rates Th-230[3] (Ci/yr)	U-238[4] (Ci/yr)	U-235 (Ci/yr)
Colorado								
Uravan	Umetco Minerals	Grand Junction, CO	40,470	7,500	480	3.85E-04	3.85E-05	2.7E-07
New Mexico								
Bluewater	Anaconda	Ambrosia Lake, NM	1,448,826	3,500	620	1.15E-02	1.15E-03	8.1E-06
Church Rock	United Nuclear	Gallup, NM	80,940	1,500	290	3.72E-03	3.72E-04	2.6E-06
Homestake	Homestake	Ambrosia Lake, NM	283,290	1,500	300	1.09E-03	1.09E-04	7.6E-07
Ambrosia Lake	Kerr-McGee	Ambrosia Lake, NM	566,580	7,500	237	1.72E-03	1.72E-04	1.2E-05
Utah								
Moab	Atlas	Grand Junction, CO	182,115	2,500	540	1.95E-03	1.95E-04	1.4E-06
Rio Algom	Rio Algom	Grand Junction, CO	214,491	4,500	420	1.79E-03	1.79E-04	1.3E-06
White Mesa	Umetco Minerals	Farmington, NM	101,175	25,000	981	9.75E-03	9.75E-04	6.8E-06
Washington								
Sherwood	Western Nuclear	Spokane, WA	161,880	3,500	200	6.7E-03	6.7E-04	4.7E-06
Wyoming								
FAP	American Nuc.	Lander, WY	473,499	15,000	420	2.35E-02	2.35E-03	1.6E-05
Gas Hills	Umetco Minerals	Lander, WY	756,789	25,000	310	2.77E-02	2.77E-03	1.9E-05
Highland	Exxon	Casper, WY	72,846	15,000	450	1.46E-02	1.46E-03	1.0E-05
Lucky Mc	Pathfinder	Lander, WY	242,820	25,000	220	6.31E-03	6.31E-04	4.4E-06
Petrotomics	Petrotomics	Casper, WY	566,580	3,500	570	1.44E-01	1.44E-02	1.0E-04
Shirley Basin	Pathfinder	Casper, WY	242,820	25,000	208	2.25E-02	2.25E-03	1.6E-05
Split Rock	Western Nuclear	Lander, WY	728,460	25,000	430	3.70E-02	3.70E-03	2.6E-05
Sweetwater	Minerals Expl.	Rawlins, WY	28,329	25,000	280	3.21E-03	3.21E-04	2.2E-06

1. September 1991 letter, R. Bernero (NRC) to M. Oge (EPA); July 1991 memos, K. Behling (SC&A) to A. Colli (EPA) and D. Goldin (SC&A), respectively.
2. EPA89.
3. Th-230 is assumed to be in equilibrium with Ra-226, Pb-210, and Po-210.
4. U-238 is assumed to be in equilibrium with U-234.

Source Term Determination

EPA derived airborne source terms for exposed tailings using site meteorology taken from EPA89 and the methodology suggested by NRC in Regulatory Guide 3.59 (NRC87). Table 3-1 presents these source terms. Thorium-230 is assumed to be in equilibrium with radium-226, lead-210, and polonium-210. Uranium-238 is assumed to be in equilibrium with uranium-234.

Meteorologic, Demographic, and Agricultural Data

Table 3-1 presents the source of meteorological data used as input to the calculations and the distances to the nearest residents that were used as input to COMPLY. These data were taken from EPA89. The stability array meteorological data were converted to wind roses for use by the COMPLY code.

Demographic data were taken from EPA89. If these data placed the nearest resident within 2,000 m of the site, vegetables were assumed to be grown at home. Otherwise, the distance to the vegetable farm used for the dose analysis was 2,000 m. Meat- and milk-producing farms were placed at 2,000 m. These assumptions were used to maintain consistency with the Random Survey portion of this study.

3.1.1.3 Results of the Designated Survey for Uranium Mill Tailings. The results show that, using updated estimates of windblown releases from dry tailings piles, the maximum ede calculated using COMPLY is 2 mrem/yr. This dose is primarily from the inhalation and ingestion pathways. This dose is calculated for the resident exposed to the highest offsite concentration around the Petrotomics facility in Medicine Bow, Wyoming. The results for other facilities with dry tailings piles range from 0.008 to 1 mrem/yr ede. Results for all evaluated facilities are presented in Table 3-16, located at the end of this chapter.

3.1.2 Uranium Conversion Facilities

A uranium conversion facility converts uranium oxide (U_3O_8 or yellowcake) to purified uranium hexafluoride (UF_6). Uranium hexafluoride, which is volatile at slightly elevated temperatures, is the chemical form in which uranium enters the enrichment plant.

3.1.2.1 Previous Evaluations. Currently, two commercial uranium hexafluoride (UF_6) production facilities are operating in the United States, the Allied Chemical Corporation (Allied-Signal) facility at Metropolis, Illinois, and the General Atomics facility in Sequoyah, Oklahoma (formerly owned by Kerr-McGee Nuclear Corporation). Both facilities were evaluated in EPA89. The doses calculated for the Sequoyah and Metropolis facilities were 3.6 and 2.2 mrem/yr ede, respectively.

3.1.2.2 Evaluations of Specific Facilities Made During the Reconsideration Period. Both the Sequoyah and Metropolis uranium hexafluoride production facilities were included in the Designated Survey. In support of this evaluation, the licensees supplied information on the location of the closest receptor in each of 16 compass directions and the distance to the nearest vegetable-, meat-, and milk-producing farms. All other parameters used in this study are the same as those used in EPA89.

Source Term Determination

Source terms and solubility classes used in this study and in EPA89 are averages of the measured releases for each facility for 1984 through 1987. These data, which were originally reported in semi-annual environmental monitoring reports to NRC, are presented in Table 3-2.

The plant parameters used in this study and originally in EPA89 were taken from NRC84 and NRC85b. For Allied-Signal, the stack height used, 24 m, is an average of all release points for that plant. The same stack height was used for the Sequoyah facility. A stack diameter of 0.16 m was used for both facilities.

Meteorologic, Demographic, and Agricultural Data

The stability array meteorological data used in EPA89 were converted to wind roses for use by the COMPLY code.

Site-specific demographic data locating the closest receptor in each of 16 directions were obtained from the licensee for each facility. The nearest individual at both facilities is assumed to produce vegetables at home. In both cases, the nearest milk-producing farm is located at greater than 2,000 m. Therefore, to be consistent with the assumptions used in the Random Survey study, both milk-producing farms were placed at 2,000 m.

Table 3-2. Atmospheric radioactive emissions assumed for reference dry and wet process uranium conversion facilities

Facility	Radionuclide	Emissions (Ci/y)	Solubility Class (%)[1] D	W	Y	Reference
Allied Corp. Metropolis, IL	U-Natural[2]	0.10000	56	30	14	NRC84
	Th-230[2]	0.00050	0	0	100	
	Ra-226[2]	0.00001	0	100	0	
Sequoyah Fuels Sequoyah, OK	U-Natural[3]	0.050	65	5	30	NRC85b
	Th-230[3]	0.005	0	0	100	
	Ra-226[3]	0.005	0	100	0	

1. Solubility classes D, W, and Y refer to the retention of inhaled radionuclides in the lungs; representative half-times for retention are less than 10 days for class D, 10-100 days for class W, and greater than 100 days for class Y.

2. Particle size 3.4 μm.

3.

Particle size (μm)	% (Average: 1980-1984)
4.2 to 10.2	9.3
2.1 to 4.2	9.7
1.3 to 2.1	5.5
0.69 to 1.3	6.5
0.39 to 0.69	13.5
0.00 to 0.39	55.3

Data taken from NUREG-1157 (NRC85b).

The nearest meat-producing farm is located more than 2,000 m from the Allied-Signal facility. Therefore, the meat-producing farm was placed at 2,000 m for the COMPLY analysis. However, Sequoyah Fuels maintains a "stocker operation" in which cattle are rotated through different pastures to achieve a desired weight gain prior to being shipped to a feed lot. The nearest pasture used in this stocker operation is located 244 m from the nearest plant stack.

3.1.2.3 Results of the Designated Survey for the Uranium UF_6 Conversion Facilities. The maximum ede calculated using COMPLY and current detailed demographic data is 7 mrem/yr for the Allied-Signal wet process uranium conversion facility. This dose is primarily from the inhalation pathway. The maximum ede calculated for the dry process uranium conversion facility (Sequoyah Fuels Corporation) is 3 mrem/yr from the inhalation and ingestion pathways. In both cases, the most exposed individual is a resident located approximately 700 m from the facility.

3.1.3 Fuel Fabrication Facilities

There are two basic types of fuel fabrication plants: those that produce fuel assemblies for light water reactors and those that produce fuel assemblies for test and research reactors. In either case, the raw material is pelletized, encased with metal, and formed into assemblies.

3.1.3.1 Previous Evaluations.

Non-Light Water Reactor (LWR) Fuel Fabrication Facilities. None of the facilities in this category were estimated to cause doses greater than 1 mrem/yr ede to nearby individuals (EPA89).

LWR Fuel Fabrication Facilities. Table 3-3 lists the seven licensed uranium fuel fabrication facilities in the United States that fabricate commercial LWR fuel. Of the seven, only five had active operating licenses as of January 1, 1988. Of those five facilities, two use enriched uranium hexafluoride to produce completed fuel assemblies and two use uranium dioxide. The other facility converts UF_6 to UO_2 and recovers scrap materials generated in the various processes of the plant.

In EPA89, the site characteristics used in the assessment of the reference fuel fabrication facility were drawn from a combination of the Westinghouse (Columbia, South Carolina) and General Electric (Wilmington, North Carolina) facilities. This is appropriate since all phases of fuel fabrication (i.e., both ammonium diuranate wet process and direct-conversion dry process conversion of UF_6 to UO_2, mechanical fabrication of fuel assemblies, and scrap recovery) take place at these sites. The dose calculated for this model fuel fabrication facility was 0.27 mrem/yr ede.

3.1.3.2 Evaluations of Specific Facilities Made During the Reconsideration Period.

Non-Light Water Reactor (LWR) Fuel Fabrication Facilities. For non-LWR fuel fabricators, the doses were found to be very low (EPA89). Consequently, evaluations of these facilities were not updated.

LWR Fuel Fabrication Facilities. The EPA89 study emissions data were developed so that the model fuel fabrication facility assessed would represent the bounding case for

Table 3-3. Light water reactor commercial fuel fabrication facilities licensed by the Nuclear Regulatory Commission as of January 1988.

Licensee	Facility Location	Operations	Process Used to Convert UF_6 to UO_2	Final Product	1980 Operating Capacity (t/yr)	Active Operating License as of June 1987
Advanced Nuclear Fuels	Richland, WA	LEU[1] Conversion (UF_6 to UO_2), Fabrication & Scrap Recovery; Commercial LWR Fuel	Dry & Wet	Complete fuel assemblies	650	No
Babcock & Wilcox - CNFP	Lynchburg, VA	LEU Fabrication; Commercial LWR Fuel	----	Complete fuel assemblies	250[2]	Yes
Babcock & Wilcox	Apollo, PA	Authorized Decontamination; Pending Nuclear Reactor Service Operations	Wet	UO_2 powder	250	No
Combustion Engineering	Windsor, CT	LEU Fabrication; Commercial LWR Fuel	----	Complete fuel assemblies	150[2]	Yes
Combustion Engineering	Hematite, MO	LEU Conversion (UF_6 to UO_2) & Scrap Recovery	Dry	UO_2 powder	150	Yes
General Electric	Wilmington, NC	LEU Conversion (UF_6 to UO_2), Fabrication; & Scrap Recovery:Commercial LWR Fuel	Dry & Wet	Complete fuel assemblies	1,500	Yes
Westinghouse Electric	Columbia, SC	LEU Conversion (UF_6 to UO_2), Fabrication & Scrap Recovery; Commercial LWR Fuel	Dry & Wet	Complete fuel assemblies	750	Yes
				Total	3,300	

1. Low enrichment uranium.
2. Conversion of UF_6 to UO_2 takes place at separate feed plants; therefore, capacity is not counted in the total.

LWR fuel fabricators. However, past evaluations of the "worst case" model facility did not utilize detailed close-in, site-specific demographic data. During the reconsideration period, EPA obtained and used updated demographics that located the closest receptor in each of 16 compass directions for the Westinghouse fuel fabrication facility. The distance to the nearest vegetable-, meat-, and milk-producing farms was also obtained as part of the Designated Survey. All other data utilized in this study were taken from EPA89.

Source Term Determination

Table 3-4 presents reported uranium effluents from 1983 through 1987 for each of the fuel fabrication facilities with current operating licenses. These data, taken from EPA89, were originally reported in the semi-annual environmental monitoring reports submitted by the facilities to NRC. The data in Table 3-4 show that the Westinghouse and General Electric facilities have releases 10 to 100 times those of the Babcock and Wilcox and Combustion Engineering facilities. This is expected because the Westinghouse and General Electric plants produce substantially more fuel and start the process with uranium hexafluoride, while the other two facilities begin the fuel fabrication process with UO_2.

The atmospheric radioactive emissions estimated to be released each year by the reference fuel fabrication facility analyzed in EPA89 are presented in Table 3-5. With the exception of uranium-236, these values represent the geometric mean of the reported effluent releases for the Westinghouse fuel fabrication facility for 1983 through 1987. The geometric mean best represents the radioactive emissions, since the sample distribution is lognormal.

The value for uranium-236 is based on release data for 1983 through 1987 as reported in the semi-annual environmental monitoring reports submitted to NRC by the General Electric facility at Wilmington, North Carolina. The effluent release height used in this analysis is 10 m (EPA89).

Meteorologic, Demographic, and Agricultural Information

The climatological data used originally in EPA89 are based on measurements taken at the U.S. Weather Bureau Station at Columbia Metropolitan Airport in South Carolina (NRC85a). Sets of hourly meteorological data obtained from the airport for 1984 through 1986 were used to develop wind frequency distributions for stability classes A through F. Those same stability arrays were converted to a wind rose for use with the COMPLY code.

Table 3-4. Light water reactor commercial fuel fabrication facilities reported annual uranium effluent releases for 1983 through 1987 in μCi/yr.[1]

Licensee	Year	U-234	U-235	U-236	U-238	Total
Babcock and Wilcox	1983	4.7E+00	2.1E-01	2.1E-02	1.1E+00	6.0E+00
Lynchburg, VA	1984	5.6E+00	2.5E-01	2.3E-02	1.3E+00	7.2E+00
SNM-116	1985	4.6E+00	2.1E-01	2.1E-02	1.1E+00	5.9E+00
70-1201	1986	5.7E+00	2.5E-01	2.6E-02	1.3E+00	7.3E+00
	1987	3.9E+00	1.7E-01	1.7E-02	9.1E-01	5.0E+00
Combustion Engineering	1983	NA[2]	NA	NA	NA	3.9E+01
Windsor, CT	1984	NA	NA	NA	NA	2.7E+01
SNM-1067	1985	NA	NA	NA	NA	4.9E+01
70-1100	1986	NA	NA	NA	NA	5.5E+01
	1987	NA	NA	NA	NA	4.7E+01
Combustion Eng	1983	NA	NA	NA	NA	2.1E+02
Hematite, MO	1984	NA	NA	NA	NA	4.2E+01
SNM-33	1985	NA	NA	NA	NA	7.3E+01
70-36	1986	NA	NA	NA	NA	6.7E+02
	1987	NA	NA	NA	NA	2.8E+02
General Electric	1983	3.1E+02	2.0E+01	4.5E+02	1.3E+02	4.6E+02
Wilmington, NC	1984	4.0E+02	2.6E+01	5.7E+00	1.7E+02	6.0E+02
SNM-1097	1985	4.1E+02	2.7E+01	5.7E+00	1.5E+02	5.9E+02
70-1113	1986	1.2E+03	7.1E+01	1.6E+01	3.5E+02	1.6E+03
	1987	1.6E+02	1.0E+01	2.0E+00	5.6E+01	2.3E+02[3]
Westinghouse	1983	1.2E+03	5.3E+01	NR[4]	2.5E+02	1.5E+03
Columbia, SC	1984	1.5E+03	1.2E+02	NR	3.2E+02	1.9E+03
SNM-1107	1985	1.2E+03	7.2E+01	NR	3.1E+02	1.6E+03
70-1151	1986	1.1E+03	5.3E+01	NR	3.4E+02	1.5E+03
	1987	1.0E+03	5.6E+01	NR	3.1E+02	1.4E+03

1. Taken from semi-annual licensee environmental monitoring reports submitted to NRC.
2. Not available; only total curies of uranium released reported to NRC.
3. Release data for the second half of 1987 were not available but were assumed to be the same as first half's.
4. NR denotes not reported. Values are small and not included in total.

Table 3-5. Atmospheric radioactive emissions assumptions for reference fuel fabrication facility.

Radionuclide	Emissions (Ci/yr)
U-234	1.2E-03
U-235	6.7E-05
U-236	1.6E-05
U-238	3.0E-04

Site-specific demography locating the closest receptor in each of 16 directions and the distance to the nearest vegetable-, meat-, and milk-producing farms was obtained from the licensee for the Westinghouse facility. The nearest vegetable-producing farm is located 240 m from the source. Milk- and meat-producing farms are located more than 2,000 m from the stack. To be consistent with assumptions used for the Random Survey, residents were assumed to grow all their vegetables at home, and meat- and milk- producing farms were placed at 2,000 m for this analysis.

3.1.3.3 Results of the Designated Survey for Fuel Fabrication Facilities. The maximum ede calculated using COMPLY and current detailed demographic data for the Westinghouse CNFD fuel fabrication facility in Columbia, South Carolina, is 0.06 mrem/yr. This dose is primarily from the inhalation pathway. The dose occurs to a resident located approximately 1,000 m from the facility.

3.1.4 Interim Spent Fuel Storage Facilities

The only commercial spent fuel storage facility licensed in the United States is the General Electric facility in Morris, Illinois. It is currently operating. However, the vast majority of spent fuel is stored at nuclear power reactor sites.

Interim spent fuel storage facilities were not examined separately in past evaluations but were included in the evaluation of power reactors (EPA89, EPA91). All reactor sites have wet pool storage capability, and some have additional out-of-pool capacity. EPA89 found that the overall emissions from power reactors, of which spent fuel storage was one of four sources of emissions, were well within regulatory limits. A more recent EPA study (EPA91) also found that total airborne emissions from reactor sites are very low, causing doses of less than 1 mrem/yr ede to the most exposed individual. On this basis, EPA concludes that a separate evaluation of the Morris facility is not necessary.

3.2 TEST AND RESEARCH REACTORS

As of August 1988, there were 76 non-power research and 8 test reactors licensed by NRC in the United States (NRC88a).

The majority of the research reactors are located at universities where they are used for teaching and research: to study reactor designs, to conduct research on the effects of radiation on materials, and to produce radioactive materials used by sealed source and radiopharmaceutical manufacturers. Approximately 37 percent of these are of the TRIGA design. These reactors have thermal power levels ranging from essentially zero to 10,000 kilowatts.

Table 3-6 lists the NRC docket number, thermal power level, location, and present licensing status of the eight test reactors. Two are operational. The remainder are in safe storage. Their thermal power levels range from 6 to 60 megawatts thermal (Mwt).

Table 3-6. Licensed test reactors in the United States as of August 1991.[1]

NRC Docket No.	Test Reactor Name	Thermal Power (Mw)	Location	Present Status
50-22	Westinghouse	60	Waltz Mill, PA	Safe Storage
50-30	NASA Plum Brook	60	Sandusky, OH	Dismantling Order Issued May 26, 1981
50-70	General Electric	50	Alameda County, CA	Operational (currently shut down)
50-146	Saxton PWR	28	Saxton, PA	Safe Storage
50-184	NBS	10	Gaithersburg, MD	Operational
50-183	GE EVESR Exp. Superheat	17	Alameda County, CA	Safe Storage
50-200	B&W BAWTR	6	Lynchburg, VA	Safe Storage (NRC)
50-231	SEFOR Sodium Cooled	20	Strickler, AR	Safe Storage (State)
1. List taken from NRC82; status verified August 1991.				

3.2.1 Previous Evaluations

Previous evaluations (EPA79, EPA84, EPA89) show that the emissions from these facilities are a function of power level and duty cycle.

In EPA89, doses resulting from test and research reactors were bounded on the basis of the four actual reactors with the largest emissions as identified by Corbit (Co83). These included three university research reactors (Massachusetts Institute of Technology, University of Missouri, and University of Rhode Island) and one government test reactor (the National Bureau of Standards[4]). Emissions data from Corbit were supplemented by information presented in the facilities' annual operating reports (e.g., MIT87). The principal nuclide emitted is argon-41. Tritium is also emitted, although in lesser amounts. The emissions result in a maximum estimated dose of 0.7 mrem/yr ede (EPA89).

3.2.2 Evaluations of Specific Facilities Made During the Reconsideration Period

Of the four reactors that were evaluated in EPA89, only three are currently operational (Massachusetts Institute of Technology [MIT], University of Missouri, and the National Institute of Standards and Technology [NIST] reactors). These three remaining reactors were included in the Designated Survey. As part of the reevaluation, detailed demographics were obtained from the licensees. All other parameters used were taken from the EPA89 assessment.

Source Term Determination

The current study used the same effluent release data as EPA89. These data are shown in Table 3-7.

Table 3-7. Effluent release rates (Ci/yr) for test and research reactors.

Facility	Radionuclide	
	H-3	Ar-41
University of Missouri	1.6E+01	2.5E+03
National Institute of Standards & Technology	1.6E+02	4.7E+02
Massachusetts Institute of Technology	-	4.2E+03

[4] NBS is now known as the National Institute of Science and Technology.

The effluent releases occur from stacks 33 m, 33 m, and 50 m high, respectively, for the University of Missouri, NIST, and MIT reactors.

Meteorologic, Demographic, and Agricultural Data

As part of the Designated Survey, site demographic data used for the assessments presented in EPA89 were updated to incorporate information obtained from the licensees on the distance to the closest receptors in each of 16 directions. The distance to the nearest meat, milk, and vegetable farms was also obtained.

The meteorological data used in this study for the University of Missouri, NIST, and MIT reactors are for Columbia, Missouri; Fort Meade, Maryland; and Boston, Massachusetts; respectively (EPA89). For this study, the stability array data used in EPA89 were converted to wind roses for use with the COMPLY code.

Based on the COMPLY run for the University of Missouri, the receptor exposed to the highest concentration is a resident located approximately 700 m from the source. For NIST, the receptor exposed to the highest concentration is also a resident, in this case approximately 480 m distant. The COMPLY run using detailed demography showed that, for MIT, the receptor exposed to the highest concentration is a nonresident. This individual is located approximately 100 m from the source.

Agricultural data obtained from the University of Missouri indicated that a vegetable-producing farm is located 600 m from the source. The vegetable farm was placed at this location for this study. No milk- or meat-producing farms were reported within 2,000 m of the reactor. Therefore, in order to maintain consistency with the Random Survey assumptions, the milk and meat farms were placed at 2,000 m.

Agricultural data supplied by NIST and MIT indicated no farms within 2,000 m of either reactor. To be consistent with the Random Survey assumptions, the vegetable, milk, and meat farms were placed at 2,000 m.

3.2.3 Results of the Designated Survey of Test and Research Reactors

The immersion pathway is the dominant contributor to the dose for all three facilities. The maximum ede calculated using COMPLY and current detailed demographic data is 4 mrem/yr. This dose is calculated for the individual exposed to the highest offsite concentration around the Massachusetts Institute of Technology research reactor. This dose is to a nonresident in an office; therefore, an occupancy factor of 0.3 was applied. The value of 0.3 is based upon 10 hours per day, 5 days per week, 52 weeks per year (10x5x52/8760=0.3).

The ede calculated for the University of Missouri research reactor is 2 mrem/yr. The ede calculated for the receptor exposed to the highest offsite concentration around the National Institute of Standards and Technology test reactor is 0.8 mrem/yr. In both cases, the dose is to an offsite resident. Refer to Section 3.9 for a summary of all dose estimates.

3.3 RADIOPHARMACEUTICAL AND RADIOLABELED COMPOUND MANUFACTURERS

Of the approximately 120 radiopharmaceutical suppliers, distributors, and nuclear pharmacies (Ce81), 15 are large firms. These firms handle large amounts of radionuclides in hot cells, while smaller firms change the chemical form of the nuclides, and the pharmacies repackage the material into convenient amounts.

3.3.1 Previous Evaluations

The four largest firms (DuPont Boston, DuPont Billerica, Amersham, and Cintechem) were previously evaluated (EPA89). The maximum dose to nearby individuals was estimated to be 9 mrem/yr ede.

3.3.2 Evaluations of Specific Facilities Made During the Reconsideration Period

The previous evaluation of Amersham was judged to be adequate; therefore, it was not re-evaluated as part of this study. Because Cintechem has shut down and is decommissioning its production reactor, it was not included in the current evaluation. In March 1991, DuPont Boston and DuPont Billerica were re-evaluated using updated information obtained from the licensees (SCA91). Mallincrodt's Maryland Heights,

Missouri, facility, a large facility not analyzed in EPA89, was also included in the March 1991 study. All data and results presented here for these facilities were taken from SCA91.

Source Term Determination

Operations at the DuPont Boston facility are housed in several multi-story buildings on two city blocks, across the street from each other. Each block contains several buildings and a large parking lot. The first group of buildings handles virtually all the radioactivity and has five roof-top stacks, serving 140 hoods and hot cells. Three stacks are on one building; two stacks are on a second building. For dose calculations, these were modeled as two stacks (18 m and 24 m high), one for each building. This study used the emission data obtained from Dupont Boston for 1989. The 1987 release data are shown for comparison in Table 3-8.

Table 3-8. Dupont Boston emission data.[1]

Nuclide	Release Rate (Ci/yr)		
	1987	1989	
		18 m	24 m
H-3	97.7	12.9	91.23
C-14[2]	4.7	1.9	4.9
C-14[3]	3.8	2.8	10.1
S-35	0.38	0.2	0.3

1. Data obtained from SCA91.
2. CO_2 chemical form.
3. Organic chemical form.

For Dupont Billerica, both 1987 and 1989 releases of iodine-125 were known. These include estimates of the releases from a waste storage warehouse. These values are based on DuPont's engineering estimates of the potential releases from the warehouse using on ambient air monitoring results and estimated air turnover rates. Available release data for calendar years 1987 and 1989 are presented in Table 3-9. The emission data for 1987 were used for this evaluation.

Table 3-9. Dupont Billerica emission data.

Nuclide	Release Rate (Ci/yr)	
	1987	1989
Xe-133	2.84	n/a
P-32	1.6E-02	n/a
S-35	1.6E-02	n/a
I-125	2.0E-02	1.9E-02
I-131	2.5E-02	n/a
Kr-85	9.5E-01	n/a

At DuPont Billerica, four radiological stacks serve many hoods, glove boxes, hot cells, and reaction vessels. For dose calculations, they were modeled conservatively as a single 15 m stack.

For dose calculations, the Mallincrodt facility was modeled with two roof-top stacks. Stack #1 (19 m high) models all stacks at the northwest end of the site; stack #2 (13 m high) models those at the southeast end.

Effluents for the Mallincrodt facility were provided for the 12 months ending August 31, 1989, based on measured data. Effluent values based on a calendar year were not available; however, the radiation safety officer (RSO) indicated that the values provided were representative of a typical year. Release data are provided in Table 3-10.

Table 3-10. Mallincrodt emission data.

Nuclide	Release Rate (Ci/yr)	
	13-m Stack	19-m Stack
I-131	1.5E-02	2.2E-01
I-125	-	7.0E-04
I-123	1.6E-03	1.5E-03
Tc-99m	-	7.7E-02
Mo-99	-	6.3E-03
In-111	-	1.0E-03
Ga-67	-	6.0E-04

Meteorologic, Demographic, and Agricultural Data

Dose calculations for DuPont Boston were performed using wind rose data for Logan Airport which were obtained from DuPont. Doses for DuPont Billerica were calculated using COMPLY's default mean wind speed of 2 m/sec. Dose calculations for Mallincrodt were performed using wind rose data for the St. Louis, Missouri, Airport. Mallincrodt supplied the meteorological data.

Several residences are located across the street from the Dupont Boston facility. The distance between stack #1 and one of these residences is 60 m. The distance between stack #2 and another residence is 50 m. Although not the same residence, COMPLY treats them as such. The nearest farm is assumed to be 1,000 m away. Meat, milk, and vegetable production was assumed to take place at this distance. The closest receptor to the Dupont Billerica facility is a residence located 165 m from the stack. A vegetable farm is located about 500 m from this stack. A milk and meat farm is located about 1,400 m away.

An office was identified as the closest receptor during a site visit to Mallincrodt. This office, located within the same industrial park as the licensee, is 215 m from stack #1 and 130 m from stack #2. Aerial photographs made available for inspection by Mallincrodt and onsite inspections were used to locate a vegetable garden 261 m from stack #1 (410 m from stack #2). No milk or meat farms were found within 800 m. Thus, a default distance of 800 m was used for these receptors.

3.3.3 Results of the Designated Survey for Radiopharmaceutical and Radiolabeled Compound Manufacturers

The calculations resulted in a receptor ede of 5 mrem/yr for the DuPont Boston facility. The total ede for the DuPont Billerica and Mallincrodt facilities, respectively, were 0.2 and 0.09 mrem/yr. For Mallincrodt, the dose is to a nonresident in an office; therefore, an occupancy factor of 0.3 was applied. The value of 0.3 is based upon 10 hours per day, 5 days per week, 52 weeks per year (10x5x52/8760=0.3). Refer to Section 3.9 for a summary of dose estimates.

3.4 HOSPITALS AND MEDICAL RESEARCH FACILITIES

Licensees engaged in medical diagnosis, treatment, and biomedical research constitute the largest subgroup of NRC-licensed facilities using radioactive materials in unsealed forms. The facilities within this subgroup range from individual medical practices to large medical centers. An individual physician may perform an occasional diagnostic procedure using radiopharmaceuticals, while the large medical centers may engage in extensive biomedical research using radioactive materials as well as perform diagnostic and therapeutic procedures involving radiopharmaceuticals on a daily basis.

3.4.1 Previous Evaluations

In its previous assessments of NRC-licensed facilities using radionuclides for medical purposes (EPA89), EPA focused on large hospitals and medical research facilities. Due to the quantity of radioactive materials used and the proximity of potential receptors, such facilities provide an upper-bound of the dose for this large segment of the NRC-licensed source category.

In EPA's previous assessments, data on airborne emissions from such facilities were limited. Limitations were also inherent in the near-field estimates of air concentrations provided by the Gaussian plume dispersion model incorporated in the assessment code AIRDOS-EPA. When EPA first proposed a NESHAP for NRC-licensed facilities in 1983, it attempted to identify whether the proposed standard would have an impact on medical facilities (SCA84). Based on discussions with personnel involved in nuclear medicine, EPA identified approximately 15 facilities with extensive programs. Information on these facilities was gathered to determine the concentration of radioiodines in their effluent and the location of the nearest receptors. Based on assessments of the dispersion factors needed to reduce the effluent concentrations to a level consistent with the proposed standard, it was concluded that the facilities could comply with the NESHAP without having to install additional effluent controls.

During the 1988-1989 radionuclide NESHAPs rulemaking, EPA sought to overcome the limitations in the emissions data by evaluating the doses that could result from the largest releases from medical licensees, as reported in the database maintained by the Conference of Radiation Control Program Directors (CRCPD). Calculations performed to evaluate the

"large hospital" category in EPA89, indicated that the maximum estimated dose to nearby individuals would be approximately 0.2 mrem/yr ede. However, the evaluation cautioned that "the absence of reported radioiodine releases is common, due to the lack of effluent monitoring at hospitals." When coupled with the limitations of the assessment code in evaluating near-field concentrations, considerable uncertainty remained as to whether the releases evaluated for the "large hospital" actually bound the doses and risks caused by this class of licensees.

3.4.2 Evaluations of Specific Facilities Made During the Reconsideration Period

When the NESHAP for NRC-licensed facilities was promulgated on December 15, 1989, the Administrator announced that he was treating the concerns relating to duplicative regulation and possible adverse impacts on the availability of medical treatment raised by NRC and the National Institutes of Health (NIH) during the public comment period as a petition to reconsider the NESHAP. The Administrator granted this reconsideration, and the effective date of the NESHAP was stayed during the reconsideration.

Inasmuch as the concerns raised by the NIH and other commentators on the NESHAP focused on the stringency of the 3 mrem/yr ede limit for doses from radioiodines, EPA again attempted to identify medical facilities using large quantities of radioiodines. Beginning with information supplied by the medical facilities, EPA determined that the following medical centers have therapeutic and biomedical research programs that are among the largest in the country: the National Institutes of Health, Johns Hopkins Medical Center, the University of California at Los Angeles (UCLA), Washington University Medical Center, M.D. Anderson Medical Center, the University of Wisconsin, the University of California at San Francisco (UC San Francisco), and the University of California at Irvine (UC Irvine).

Cognizant personnel at each facility, usually the Radiation Safety Officer, were contacted, and voluntary cooperation in assisting EPA was requested. Information on quantities of radioactive materials used, effluent concentrations, effluent controls employed, and locations of nearby individuals was obtained for each facility (SCA91). In several instances, site visits were arranged.

It was determined that the doses caused by releases from the M.D. Anderson Medical Center and the Washington University Medical Center, both of which employ multi-curie

quantities of radioiodines but with double or single charcoal filtration, would be bounded by the estimates for Johns Hopkins and the NIH which handle large quantities of radioiodines and do not have filtration systems. Therefore, formal COMPLY evaluations of M.D. Anderson and Washington State University Medical Centers were not performed.

Source Term Determination

Data obtained from NIH, Johns Hopkins, the University of Wisconsin, UCLA, UC San Francisco, and UC Irvine (SCA91) were evaluated using the EPA computer code COMPLY. Where measured effluent data were unavailable, source terms were estimated by multiplying the amount of each radionuclide used during a one-year period by the appropriate release fraction, as established in EPA89a. However, two facilities, UCLA and Johns Hopkins, the EPA-approved release fraction of 1 was not used for materials heated to above 100° C. Instead, the evaluation relied on release fractions determined from measurements of actual releases of the radionuclides of interest. The source terms used in the COMPLY runs are given in Table 3-11.

Meteorological, Demographic, and Agricultural Data

Johns Hopkins (SCA91): Because this facility is in an urban setting, the receptors are close to the release points. Multi-story buildings, containing both commercial stores and residences, are directly across the street from the licensee. One such building is located approximately 30 m north of the Biophysics (P-B) and Wood Basic Sciences (WBS) buildings. Another is located 30 m north of the Traylor (T) building. Analysis showed the maximum receptor to be located 30 m north of the P-B and WBS buildings, and 153 m from the T building. Given the urban siting of the facility, it was assumed that no food production occurs within 4,500 m. Dose calculations were performed using an average wind speed of 3.17 m/s. This wind speed was based on 5-year meteorological information collected from the Baltimore-Washington International Airport, approximately 10 km from the site.

University of Wisconsin (SCA91): Demographic data obtained for this study show that the nearest receptor is a campus heat plant located 105 m to the west of the incinerator stack. Although there is an agricultural program on campus, no commercial farming is done. The nearest farms are estimated to be 1,500 m from the incinerator stack. Doses were calculated using the COMPLY default wind speed of 2 m/s.

Table 3-11. Hospital and medical research facilities effluent release rates.

Facility Name/Location	Release Point/Stack Height	Nuclide	Ci/yr
Johns Hopkins Baltimore, MD	WBS Building 51 m	H-3 C-14 Mo-99 Tc-99m P-32 S-35 Xe-133	5.0E+00 5.0E-01 2.1E-10 1.7E-03 2.1E-05 2.5E-05 15.6
	P-B Building 13 m	I-125 I-131	1.4E-02 9.5E-04
	T Building (incinerator) 51 m	Cr-51 Ce-141 Gd-153 I-125 In-114 Nb-95 Ru-103 Sc-46 Sn-113	4.0E-03 7.3E-03 8.5E-02 2.0E-03 1.3E-01 7.2E-02 6.3E-02 3.1E-02 7.7E-02
University of Wisconsin Madison, WI	Incinerator 10 m	H-3 C-14 P-32 S-35 Ca-45 I-125 I-131 Sr-85 Na-22 Sc-46 Cl-36 Cr-51 Co-57 In-111 Sn-113 Ce-141 Se-75	3.5E-02 7.9E-02 4.7E-02 3.9E-01 2.0E-02 3.3E-02 8.5E-04 2.0E-03 1.7E-03 1.4E-03 1.0E-03 1.7E-03 1.6E-03 2.4E-03 1.2E-03 2.0E-03 7.0E-05

Table 3-11 (Continued)

Facility Name/Location	Release Point/Stack Height	Nuclide	Ci/yr
UCLA Hospital Los Angeles, CA	Hospital 5 m	H-3 C-11 C-14 F-18 P-32 S-35 Ca-45 Cr-51 I-125 I-131 Mo-99 Tc-99m Xe-133 Tl-201	2.2E-03 7.0E-03 1.0E-04 32.8 6.7E-03 3.2E-03 5.0E-04 1.3E-03 1.5E-03 3.0E-03 1.6E-04 7.0E-01 6.2E+00 6.5E-03
UC San Francisco San Francisco, CA	MS Building 56 m	I-125 I-131	2.5E-03 2.0E-03
UC Irvine Irvine, CA	Nuclear Med. Building 5 m	P-32 Cr-51 Mo-99 Tc-99m I-125 I-131 Xe-133 Co-57	1.0E-04 1.0E-05 1.5E-07 6.8E-02 1.0E-04 2.0E-03 10.4 5.0E-05
NIH Bethesda, MD	NIH Complex 42 m	C-14 Cr-51 Ga-67 H-3 I-123 I-125 I-131 Mo-99 P-32 S-35 Te-99m	3.8E-04 6.5E-03 2.6E-03 2.2E-02 3.2E-05 6.7E-03 1.3E-02 3.4E-04 2.2E-02 1.9E-02 2.1E-02

UCLA (SCA91): Due to the lack of specific demographic data, the distance to the closest receptor was estimated to be 100 m. It was assumed that this receptor grows vegetables. Meat and milk farms were estimated to be at a distance of 1,000 m. Doses were calculated using the COMPLY default wind speed of 2 m/s.

UC San Francisco (SCA91): The nearest receptor is a commercial office across the street from the top of the MS building. The height of this building is 56 m. The nearest receptor is a commercial office approximately 30 m from the MS building. The location of the nearest farms was not known. It was estimated that a vegetable garden could be found 500 m away and that the distance to the nearest farms is 1,600 m. Doses were calculated using the COMPLY default wind speed of 2 m/s.

UC Irvine (SCA91): The nearest receptor was determined to be a commercial building across the street from the hospital at an estimated distance of 50 m. Estimated distances to the nearest vegetable garden and farm are 800 m and 16,000 m, respectively. The receptor is a nonresident in an office; therefore, an occupancy factor of 0.3 was applied. The value of 0.3 is based upon 10 hours per day, 5 days per week, 52 weeks per year (10x5x52/8760=0.3). Doses were calculated using the COMPLY default wind speed of 2 m/s.

NIH[5]: The nearest receptor was determined to be a resident located at a distance of 200 m. The resident is assumed to grow vegetables at home. Meat and milk farms are placed at 2,000 m. Doses were calculated using the COMPLY default wind speed of 2 m/s.

3.4.3 Results of the Designated Survey for Hospitals and Medical Research Facilities

The highest estimated dose from any of these facilities is 8 mrem/yr ede to a receptor located directly across the street from the incinerator at Johns Hopkins. Radioiodines contributed 0.4 mrem/yr ede to this total. The highest estimated ede from iodines is 1 mrem/yr. This dose was calculated for NIH. The total ede calculated for NIH was 2.0 mrem/yr; therefore, the dose from iodines constitutes 50 percent of the total. The remainder of the ede from the hospitals and research facilities included in the Designated Survey ranges from 0.03 mrem/yr to 3 mrem/yr. Refer to Section 3.9 for a summary of dose estimates.

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[5] Personal correspondence between R. Zoon (NIH) and A. Colli (EPA), November 1989.

3.5 MANUFACTURERS OF SEALED SOURCES

Sealed source manufacturers take radionuclides in an unsealed form and put them into a permanently sealed container. Two categories of sealed source manufacturers contribute to airborne emissions. The first category consists of manufacturers (eight are known) that produce sealed radiation sources other than tritium. An additional six manufacturers of this type (e.g., The Nucleus, Oak Ridge, Tennessee) use only exempt quantities of radionuclides and produce negligible emissions.

The other category of sealed source manufacturer seals tritium gas into self-luminous lights. Currently, two firms are known to perform this type of work. They are Safety Light Corporation, in Bloomsburg, Pennsylvania, and NRD, Incorporated, in Grand Island, New York. Both facilities are located in industrial areas. They rely heavily on engineered safeguards to prevent releases of radionuclides.

3.5.1 Previous Evaluations

Three tritium light sealed source manufacturers, Safety Light Corporation in Bloomsburg, Pennsylvania, NRD in Grand Island, New York, and GE Lighting Group in Cleveland, Ohio, were originally evaluated in EPA89. One manufacturer, GE Lighting Group, has since gone out of production. The evaluations reported in EPA89 estimated the highest dose to nearby individuals from non-tritium sealed source manufacturers to be 1.0E-04 mrem/yr ede, and from tritium sealed source manufacturers to be 6.0 mrem/yr ede.

3.5.2 Evaluations of Specific Facilities Made During the Reconsideration Period

In EPA89, a model facility was used to represent manufacturers that produce non-tritium sealed radiation sources. Since EPA89 was prepared, an actual facility, Neutron Products (Dickerson, Maryland) which is a major producer of cobalt-60 sealed sources, has been identified as a large manufacturer of non-tritium sealed sources. This facility was evaluated based on emissions data and demography information supplied by the licensee. The findings are incorporated in this study.

Source Term

Sealed Sources/Non-Tritium: Neutron Products is a major producer of cobalt-60 sealed sources. All operations with possible airborne emissions are conducted in the hot cell. All site releases are exhausted from a single vent, which is located approximately 7 m above the ground. The exhaust rate is 23 m^3 per minute (800 cfm).

The effluent exhaust from the hot cell passes through a roughing filter and two HEPA filters mounted in series. The exhaust vent was recently equipped with a continuous monitoring system. The sampling is isokinetic, drawing 0.03 m^3 per minute (1 cfm) through a fiber filter. The filter is changed at least weekly and counted using single-channel gamma spectrometry.

The sampling system described above is reported to have a minimum detection limit (MDL) of 1E-12 μCi/ml, approximately 0.3 percent of the MPC for insoluble forms of cobalt-60. All measurements with this new system show activity below the MDL. The 1989 source term for the facility is estimated to be 1.2E-05 Ci/yr (see Table 3-12), assuming the MDL for the concentration in the effluent and a continuous flow rate of 23 m^3 per minute (800 cfm).

Sealed Sources/Tritium: Because effluent data for 1984 were available for each tritium lighting producer when the EPA89 analysis was being done, no model facility was needed. The emissions data used in the analysis are also shown in Table 3-12.

Table 3-12. Effluent release rates (Ci/yr) for sealed source manufacturers.

Radionuclide	Neutron Products	NRD, Inc.	Safety Light Corp.
H-3	-	3.4E+02	2.2E+03
Co-60	1.2E-05	-	-
Ni-63	-	8.0E-06	-
Po-210	-	1.4E-04	-
Am-241	-	6.1E-05	-

Meteorological, Demographic, and Agricultural Data

The meteorological data used in this study for NRD and Safety Light were originally collected at Buffalo, New York, and Harrisburg, Pennsylvania, respectively. The stability array data for these locations, that had been used in EPA89, were converted to wind roses for use with the COMPLY code. Neutron Products was evaluated using the default values of 25 percent frequency of wind towards the receptor and a wind speed of 2 m/s.

Demographic data obtained for Neutron Products show several farms in the area. The nearest residence is a farm approximately 120 m from the vent. All meat, milk, and vegetable production was assumed to occur at that location.

Detailed demographic data were obtained for NRD and for Safety Light Corporation. Based on the COMPLY runs, the receptor near NRD who is exposed to the highest concentration is a resident located approximately 170 m from the stack. At Safety Light, this individual is a resident located 190 m from the release point.

Agricultural information supplied by the NRD and Safety Light facilities indicates that there are no farms located within 2,000 m of either site. Doses for both facilities were calculated assuming that the residents produce all their own vegetables and that meat and milk production occurs on farms located at 2,000 m. These assumptions were made to maintain consistency with the Random Survey portion of this study.

3.5.3 Results of the Designated Survey for Manufacturers of Sealed Sources

The results from the COMPLY model for the non-tritium sealed source manufacturer (Neutron Products), using the source term of 1.2E-05 Ci/yr, actual vent and building dimensions, and a default wind speed of 2 m/s, indicate that the receptor ede would be 0.007 mrem/yr. The dominant pathway is exposure to contaminated ground.

The maximum ede for a tritium light sealed source manufacturer is calculated for Safety Light Corporation. Using the source term described above, a release height of 10 m, and meteorological data from Harrisburg, Pennsylvania, the ede calculated by COMPLY for the maximum individual is 3.5 mrem/yr. Most of the dose results from the inhalation and ingestion pathways.

At NRD, the receptor for whom the highest dose is calculated is a resident. Assuming the source term described above, a release height of 10 m, and meteorological data from Buffalo, New York, the ede calculated by COMPLY for the maximum individual is 0.05 mrem/yr. Inhalation is the primary pathway of exposure.

3.6 TESTING OF DEPLETED URANIUM MUNITIONS

The processing of natural uranium to obtain uranium enriched in the uranium-235 isotope results in abundant tails referred to as depleted uranium. The density and low specific activity of depleted uranium make it useful for several applications, including radiological shielding, counterweights in aircraft, and in military munitions. This latter activity has the greatest potential to release radioactive material to the air.

The military uses depleted uranium in munitions designed to pierce armor plating. The design of these munitions is developed and refined by the Army based on "soft" and "hard" testing. Soft testing is conducted to define and refine the accuracy of the munitions. The tests are done on outdoor firing ranges where the depleted uranium round is fired at the "target" located in a sand-filled testing enclosure several kilometers from the gun. After impact, the depleted uranium "rod," which is generally intact, is simply left in the ground as the risk from unexploded munitions makes retrieval too dangerous. Hard testing is conducted to evaluate and refine the destructive capability of the munitions. In hard testing, either actual munitions or scale mockups are fired at an armor-plated target. By license conditions, all hard testing of depleted uranium munitions is conducted in indoor test enclosures; the ventilation stacks of which are equipped with roughing and HEPA filters; the exhaust is monitored during testing.

The Department of Defense tests depleted uranium munitions at a number of proving grounds around the country. The Army's Ballistic Research Laboratory and Combat Systems Test Activity facilities at the Aberdeen Proving Ground in Aberdeen, Maryland, conduct both hard and soft testing. The Army also conducts soft testing at the Yuma Proving Ground near Yuma, Arizona, and at the Jefferson Proving Ground near Madison, Indiana; the Navy conducts soft test firings at the Naval Weapons Center at China Lake, California. Once every several years, the Army conducts an open-air hard test firing at the Nevada Test Site.

The Aberdeen Proving Ground conducts the greatest number of test firings. Because it is also very close to many residences, EPA considers Aberdeen to be the bounding case for this category.

3.6.1 Previous Evaluations

This source category of airborne radionuclide emissions was not previously evaluated because it was believed unlikely that munitions testing could create emissions in the respirable range. However, to remove any uncertainty, this source category was evaluated in this study.

3.6.2 Evaluations of Specific Facilities Made During the Reconsideration Period

A site visit to the Aberdeen facility was conducted during the course of this reconsideration. The releases from the test firing of depleted uranium munitions include stack releases from the indoor test enclosures used for hard firings and releases to the ambient air from the soft testing target enclosures, which may occur when the depleted uranium rods land. Given the size of the rods left in the enclosures (on the order of 1 to 8 kilograms), releases due to resuspension are not a problem, as confirmed by ambient air monitoring conducted by the Army. Monitoring data on the stack releases from the indoor testing enclosure, along with stack parameters and distances to the nearest receptors, were obtained directly from the Army (DA92).

Source Term

The emissions used in the analysis are shown in Table 3-13. These emissions represent monitored stack release data from indoor testing enclosures as provided by the Army.

Meteorological, Demographic, and Agricultural Data

The meteorological information is stability array data from Aberdeen, Maryland. The distances to the nearest residences or office, school, or business for each of the operations listed in Table 3-13 are provided in Table 3-14.

Table 3-13. Source term used for Aberdeen Proving Ground.

Operation	U-238 Release Rate, Ci/yr[1]
Range 9	6.6E-07
Range 14	1.2E-07
Range 14A	1.2E-07
Range 110E	4.5E-08
Abrasive Blaster	8.9E-07
BTD Enclosure	1.8E-06
Superbox	5.7E-05
Cut Box	1.6E-05

1. It was assumed that Th-234 and Pa-234m were also released at the same rate as the U-238 as they are in secular equilibrium.

Table 3-14. Distances to receptors at Aberdeen Proving Ground.

Operation	Distance, m
Range 9	5000 (R)[1]
Range 14	7000 (R)
Range 14A	7000 (R)
Range 110E	200 (R)
Abrasive Blaster	1200 (B)
BTD Enclosure	1100 (B)
Superbox	1000 (B)
Cut Box	1000 (B)

1. R indicates residence; B indicates business.

All farms are located at greater than 2,000 m; however, all vegetables were assumed to be grown at the home of the closest individuals.

3.6.3 Results of the Designated Survey for Testing of Depleted Uranium Munitions

The dose received by the maximally exposed individual in proximity to the Aberdeen Proving Grounds is 6E-04 mrem/yr ede.

3.7 RARE EARTH AND THORIUM PROCESSORS (SOURCE MATERIAL)

Approximately 10 licensed rare earth processors are engaged in the recovery of metals from source materials. Of the 10 facilities licensed to process rare earths, only three are operating. These three form the basis for this study: Cabot-Boyerton, Molycorp-York, and Shieldalloy-Newfield. The doses resulting from the operations of rare earth processors were assessed using the actual emissions and site characteristics for the three facilities.

Rare-earth elements are metals possessing distinct individual properties which make them potentially valuable as alloying agents. The name rare earths is deceiving, however, because they are neither rare nor earths. Rare earth minerals exist in many parts of the world, and the overall potential supply is essentially unlimited.

Rare earth facilities possessing NRC Source Material Licenses process natural and synthetic ores which contain at least 0.05 percent, by weight, of naturally occurring uranium and thorium. The principal environmental impacts of rare earth facility operations include the potential release of radioactive particles and radon from the storage, handling, and processing of the ores. The operation of a rare earth facility involves grinding, dissolving, and processing the natural and synthetic ores. These are relatively closed processes, and it is generally believed that very limited amounts of radioactivity escape. These facilities utilize various methods to store the radioactive wastes. The wastes are often stored on-site in barrels or slag piles.

3.7.1 Previous Evaluations

EPA conducted a screening assessment in 1983 and concluded that rare earth and thorium processors did not pose a public health risk (EPA83). However, EPA decided to reduce the uncertainty associated with the 1983 evaluation.

NRC conducted an evaluation of Cabot-Boyerton (NRC88). The rate of release of the materials had not been previously determined, so conservative assumptions were made. Doses were estimated using AIRDOS. For the nearest individual (350 m), the total-body dose of 0.046 mrem resulted primarily from the inhalation (54 percent) and ingestion (30 percent) pathways. The highest dose was to the lungs (0.48 mrem).

In 1985, the Oak Ridge Associated Universities conducted a radiological study of Molycorp-York (ORAU85). The summary noted that air monitoring at two process stacks indicated that radioactive emissions from plant operations were within licensed limits. The ORAU study also noted that residues from plant processes are stored in onsite low-level waste drums and a residue pile located in the southeast corner of the site.

3.7.2 Evaluations of Specific Facilities Made During the Reconsideration Period

Cabot-Boyerton: This facility is located in a rural setting in southeastern Pennsylvania, 2.4 km northeast of Boyertown. Ores are processed in order to extract tantalum and niobium. Typical concentrations of uranium and thorium range from 0.04 percent to 0.5 percent by weight. Surface radiation dose rates typically range from 0.1 mrem/hr to 2 mrem/hr.

Raw ores are ground into a flour-like consistency and then transferred into digester tanks which selectively dissolve the tantalum and niobium. The unwanted uranium and thorium react with the acid to form insoluble uranium and thorium fluorides. Particles less than 10 μm in diameter are exhausted through the 90 percent efficient dust-collection system. Up to 100 g/d of respirable particles might enter the atmosphere. After dissolution, the mixture passes through filters where the insoluble material (containing the uranium and thorium) is removed from the solution and collected for disposal.

The sludge is temporarily stored in open portable carts until a truckload of filled containers is collected and transported to above-ground concrete storage buildings. Each building is open-air vented where the roof meets the side walls to prevent radon gas from accumulating inside the building.

Cabot does not have a formal environmental monitoring program, and routine outside air monitoring has not been conducted. It is thought that the operating procedures and emission controls combine to limit radiological airborne releases to low levels. However, no monitoring data are available to confirm this. NRC does not require any offsite environmental monitoring program due to the limited effects expected.

Molycorp-York: This facility, active since the mid-1960s, is located in an urban area. The Molycorp plant carries on three basic processes, all of which involve low

concentrations of source material. All three processes operate under the same basic theory, although only one is now operating. The main working process at Molycorp converts code 5300 cerium mineral concentrate into a line of 95 percent pure cerium products. The cerium concentrate process feed material is a dry powder. Thorium and uranium are present at about 0.225 percent and 20 ppm, respectively. A typical cerium reaction charge is 1,800 kg per digest tank, containing about 0.4 kg each of thorium and uranium. All chemical processing after the initial feed dissolution is wet processing, thereby reducing airborne particulates.

After the dissolution process, thorium and uranium remain as insoluble byproducts. These byproduct materials, containing about 50 percent moisture, are shoveled into 208-liter (55-gallon) plastic drums for storage. Approximately 145 barrels (52,200 kg) are produced per month.

In order to reduce airborne particles, a 0.8 m diameter, 4.3 m high, wet scrubber is used at the cerium feed point to capture any dust and recycle it back into the system. The scrubber is equipped with an 85 m^3 per minute (3,000 cfm) blower and circulates 170 lpm (45 gpm) of scrubbing solution over the packed bed. Employees are periodically monitored at the points of greatest exposure to radioactive dust. Results show that the radiation dose to plant personnel is low; therefore, Molycorp expects that the dose to the surrounding population is minimal. There is no routine monitoring program for effluents into the atmosphere. The dust collectors and scrubbers are inspected periodically, but the inspections are usually only visual, without monitoring of the effluents.

Shieldalloy-Newfield: This active facility is located in a rural area. Shieldalloy manufactures a variety of specialty ferro-alloys, using the raw material ferro-niobium (Fe-Nb). Waste slag is separated from the nonradioactive slag and stored in two separate piles. A large quantity of material has accumulated since operations began in 1955.

Processing activities generate airborne dusts, containing low concentrations of radionuclides from the thorium and uranium decay series. Exhaust air from the processing area passes through 10,000 m^3/min baghouse dust collectors before its release to the environment. The maximum amount processed per day would be about 400 μCi of thorium and about 3.6E+08 g of natural uranium. The bags are 98 percent efficient. Shieldalloy uses an air sampler to monitor releases.

There is no indication that the waste slag piles are stabilized or have any sort of cover on them. The most likely pathway and source of contamination appears to be overland runoff from the pile. Sample analysis was underway as of August 14, 1991. Shieldalloy will also perform a risk assessment of offsite contamination, and remediation of both the radiological and chemical contamination will be evaluated. Following cleanup, the source material will be stabilized. No measures have been taken so far to keep additional low levels of radiological contamination from being transported off site. NRC has also requested Shieldalloy to provide a plan that would demonstrate compliance with the stricter limits proposed in 10 CFR Part 20 (effective January 1994), and also with NESHAPs. Shieldalloy considers perimeter air sampling sufficient to demonstrate compliance.

Source Term Determination

The three operating rare earth processors were surveyed by EPA. Molycorp and Shieldalloy supplied process source term data in response to the survey. Comparable information was not available for Cabot Corporation. Instead, site meteorology was used in conjunction with the methods in Regulatory Guide 3.59 to derive the airborne source term for sludge that is stored in open-air vented mausoleums. Table 3-15 presents the source terms used in this study.

Table 3-15. Rare earth processors' annual release rates.

Facility	Release Point	Stack Height (m)	Natural Thorium[1] (Ci/yr)	Natural Uranium[2] (Ci/yr)
Cabot Corp.	Mausoleums	1	7.6E-07	1.3E-06
Molycorp, Inc.	Tank Room	10	1.5E-06	4.0E-08
	Waste Treatment	5	7.0E-05	3.0E-06
	Moly Building	2	2.0E-07	2.5E-09
Shieldalloy	Department 111	12.2	3.0E-04[3]	7.9E-05[4]

1. Th-232 assumed to be in equilibrium with its progeny.
2. U-238 assumed to be in equilibrium with its progeny. U-235 value assumed to be 0.71% of the U-238 value. U-235 assumed to be in equilibrium with its progeny.
3. Value reported as Th-232 only.
4. Value reported as U-238 only.

Meteorologic, Demographic, and Agricultural Data

The meteorological data used in this study for Cabot Corporation, Molycorp, and Shieldalloy were originally collected at Reading, Pennsylvania; Harrisburg, Pennsylvania; and Millvalle, New Jersey; respectively. These data, which were in the form of stability arrays (EPA89), were converted to wind roses for use with the COMPLY code.

Demographic data obtained for Cabot Corporation indicated that the nearest resident is approximately 270 m from the mausoleums used to store sludge. Vegetables were assumed to be grown at this location. There are no milk- or meat-producing farms within 2,000 m. Therefore, to maintain consistency with the assumptions used for the Random Survey, milk- and meat-producing farms were placed at 2,000 m.

Demographic data obtained for Molycorp showed that the individual closest to the tank room is a resident located at a distance of 100 m. The individual closest to the waste treatment building is a non-resident located at a distance of 200 m, and the individual closest to the Moly building is a resident located at a distance of 100 m. Residents were assumed to produce their vegetables at home. There are no milk- or meat-producing farms within 2,000 m of the facility. Therefore, to be consistent with the assumptions used for the Random Survey, milk- and meat-producing farms were placed at 2,000 m.

Demographic data for Shieldalloy indicated that the closest individual is a resident located 225 m from the facility. Residents were assumed to produce their vegetables at home. There are no milk- or meat-producing farms within 2,000 m of the facility. Therefore, to maintain consistency with the assumptions used for the Random Survey, milk- and meat-producing farms were placed at 2,000 m.

3.7.3 Results of the Designated Survey for Rare Earth and Thorium Processors

The receptor exposed to the highest offsite concentration for Shieldalloy and for Cabot Corporation is a resident. At Molycorp, this individual is a non-resident; therefore, a 0.3 factor was applied to the dose calculated by COMPLY.[6] The maximum ede is calculated for Shieldalloy Metallurgical Corporation; the dose received by this individual is

[6] The value of 0.3 is based upon 10 hours per day, 5 days per week, 52 weeks per year (10x5x52/8760=0.3).

1.6 mrem/yr. The edes calculated for Molycorp and Cabot are 0.56 and 0.01 mrem/yr, respectively. Inhalation is the dominant exposure pathway for all three facilities. Refer to Section 3.9 for a summary of dose estimates.

3.8 COMMERCIAL LOW-LEVEL RADIOACTIVE WASTE DISPOSAL AND INCINERATION

Many users of unsealed radioactive materials will generate solid, low-level radioactive wastes (LLW) that require disposal. Such wastes may be incinerated on site or packaged and shipped off site to a licensed low-level waste disposal facility.

LLW is generated from a variety of commercial sources: research, power plants, diagnostic and therapeutic medicine, manufacturing, and others. When contaminated through contact with radioactive material, items such as paper, clothing, plastics, power reactor liquids, and medical fluids are classified as LLW.

Waste Brokers

Waste receivers and shippers (sometimes called "waste brokers") are primarily collection and shipping agents for facilities generating LLW. Most such receiving-shipping facilities simply collect the wastes from a number of waste-generating facilities in shipping containers approved by the Department of Transportation, monitor the packages for contamination, and hold the wastes at a warehouse until they arrange a shipment to a licensed disposal site. The licenses of most such receiving and shipping facilities do not allow the facility to repack or even open the waste packages. However, several such facilities are licensed to open, compact, and repackage waste materials before shipment.

Incinerators

Most airborne effluents from handling LLW come from incinerators. The practice of evaporating disposal site liquids has ceased, so this is no longer a source of releases to air. Although incineration is done primarily by hospitals and large research laboratories (about 100 such medical incinerators are operating - EPA89), this section deals exclusively with incinerators licensed specifically for commercial use.

Disposal Facilities

Some radionuclides may also be emitted from LLW disposal sites. Currently, only three sites (Barnwell, South Carolina; Beatty, Nevada; and Richland, Washington) are operating. Disposal of LLW is controlled by the Low-Level Radioactive Waste Policy Act of 1980 and its 1985 amendment. Any state that wishes to dispose of its LLW may join an interstate compact or design its own facility in accordance with 10 CFR 61, among other options.

LLW disposal sites do not accept spent reactor fuels, but may accept special nuclear materials and transuranics meeting the classification requirements in 10 CFR Part 61. The majority of LLW comes from power reactor operations, laboratory research, and medical facilities.

Currently operating disposal sites typically consist of a large fenced burial area with buildings for decontamination, maintenance, and waste preparation in one location. Wastes are usually buried in the transport containers in which they arrive, which minimizes releases to the atmosphere. The buried wastes are covered by overburden. New facility designs being proposed typically use a liner and a clay and/or concrete cap in addition to engineered barriers.

3.8.1 Previous Evaluations

Both incinerators (EPA89) and disposal facilities (EPA79, EPA84) have been previously investigated. Airborne emissions from waste brokers are judged to be bounded by the operation of burial and incineration facilities.

Previously, EPA's evaluation of incinerators was limited to those which were part of hospital and medical research facilities because no commercial LLW incinerators existed. Since EPA89, a commercial LLW waste incinerator has been licensed and is included in this study.

The potential public health impacts of the release of radioactive materials into ambient air from LLW burial sites have been evaluated previously (EPA79, EPA84). The doses received by the most exposed members of the public were found to be below the limits established in the NESHAP.

3.8.2 Evaluations of Specific Facilities Made During the Reconsideration Period

EPA investigated the LLW disposal process by evaluating the quarterly emissions reports of licensees for operating facilities and reviewing the license application of newly proposed LLW waste compact facilities.

For operating LLW disposal sites (Hanford, Barnwell, and Beatty), EPA confirmed its prior analyses (EPA79, EPA84) through conversations with state radiation control officers.[7]

For compact sites, EPA reviewed the NESHAP applications submitted by U.S. Ecology for the disposal site proposed for Needles, California, and by Bechtel for the site proposed for Butte, Nebraska. The applications were prepared following conservative EPA guidelines (EPA89a). For example, for the Needles application, it was assumed that the nearest receptor produces his own vegetables, meat, and milk at his home.

For incineration, EPA investigated the SEG incinerator located in Oak Ridge, Tennessee. Quarterly data include radionuclide content in waste incinerated, stack effluent, scrubber effluent, and ash generated. EPA's review was based on data reported during the 12 months of 1990. Independent analyses were not performed.

3.8.3 Results of the Designated Survey for Waste Disposal and Incineration

Environmental monitoring results for the operating LLW disposal sites indicate that releases above background have not been detected. As a result, no COMPLY calculations were made for these sites.

For the proposed compact LLW disposal sites, the dose to the nearest receptor is estimated to be 7E-01 mrem/yr ede and 6E-01 mrem/yr ede from radioiodines for the Butte, Nebraska, site (USE91). For the Needles, California, site, the dose is estimated to be 7E-01 mrem/yr ede and 7E-01 mrem/yr ede due to iodine (USE89).

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[7] Mr. L. T. Skoblar of SC&A held conversations with the following persons during February 1992: Mr. Virgil Autry, South Carolina; Mr. John Vaden, Nevada; and Mr. Gary Robertson, Washington.

For incineration operations, the dose to the maximally exposed individual is established at less than 7E-03 mrem/yr ede, with 3E-04 mrem/yr ede from radioiodines (SEG91).

3.9 SUMMARY OF RESULTS

Table 3-16 summarizes all doses estimated as part of the Designated Survey. As in previous EPA assessments of actual facilities, the NRC licensees studied are found to be currently meeting the dose limits of Subpart I.

Table 3-16. Summary of Designated Survey doses.

Type of Facility	Company & Facility Name	Total ede[1] (mrem/yr)	Iodine ede (mrem/yr)
Uranium Tailings	American Nuclear Corp Federal American Mill Riverton, WY	3E-01	N/A
	Anaconda Anaconda Mill Bluewater, NM	6E-01	N/A
	Atlas Moab Mill Moab, UT	1E-01	N/A
	Exxon Highland Mill Douglas, WY	1E-01	N/A
	Homestake Homestake Mill Grants, NM	2E-01	N/A
	Kerr McGee Kerr McGee Mill Ambrosia Lake, NM	4E-02	N/A
	Minerals Exploration Sweetwater Mill Rawlins, WY	4E-02	N/A
	Pathfinder Lucky Mc Mill Riverton, WY	6E-02	N/A
	Pathfinder Shirley Basin Mill Casper, WY	2E-01	N/A
	Petrotomics Petrotomics Mill Medicine Bow, WY	2E+00	N/A
	Rio Algom Rio Algom Mill La Sal, UT	4E-02	N/A
	Umetco Minerals Gas Hills Mill Riverton, WY	3E-01	N/A
	Umetco Minerals White Mesa Mill Blanding, UT	2E-01	N/A
	Umetco Minerals Uravan Mill Uravan, CO	8E-03	N/A

Table 3-16. (Continued)

Type of Facility	Company & Facility Name	Total ede[1] (mrem/yr)	Iodine ede (mrem/yr)
	United Nuclear Church Rock Mill Church Rock, NM	3E-01	N/A
	Western Nuclear Sherwood Mill Wellpinit, WA	2E-01	N/A
	Western Nuclear Split Rock Mill Jeffrey City, WY	4E-01	N/A
UF_6 Plants	- Wet Process Allied-Signal Inc. Metropolis, IL	7E+00	N/A
	- Dry Process Sequoyah Fuels Corp. Gore, OK	3E+00	N/A
Fuel Fabrication Facility	Westinghouse CNFD Columbia, SC	6E-02	N/A
Test & Research Reactors	National Institute of Standards and Technology Gaithersburg, MD	8E-01	N/A
	University of Missouri Columbia, MO	2E+00	N/A
	MIT Cambridge, MA	4E+00[2]	N/A
Radiopharmaceutical Manufacturers	DuPont Boston Boston, MA	5E+00	N/A
	DuPont Billerica Billerica, MA	2E-01	< 2E-01
	Mallincrodt Maryland Heights, MO	9E-02[2]	9E-02
Hospital & Medical Research Facilities	NIH Bethesda, MD	2E+00	1E+00
	UCLA Los Angeles, CA	3E+00	1E-01
	UC Irvine Irvine, CA	3E-02[2]	< 3E-02
	Johns Hopkins Baltimore, MD	8E+00	4E-01
	University of Wisconsin Madison, WI	6E-01[2]	6E-02

Table 3-16. (Continued)

Type of Facility	Company & Facility Name	Total ede[1] (mrem/yr)	Iodine ede (mrem/yr)
	UC San Francisco San Francisco, CA	3E-02[2]	< 3E-02
Manufacturers of Sealed Sources	Safety Light Corp Bloomsburg, PA	4E+00	N/A
	NRD, Inc. Grand Island, NY	5E-02	N/A
	Neutron Products Dickerson, MD	7E-03	N/A
Testing of Depleted Uranium Munitions	Aberdeen Proving Grounds U.S. Army Aberdeen, MD	6E-04	N/A
Rare Earth & Thorium Processors	Molycorp, Inc. York, PA	6E-01[2]	N/A
	Cabot Corporation Boyertown, PA	1E-02	N/A
	Shieldalloy Metallurgical Corp Newfield, NJ	2E+00	N/A
Commercial Low-Level Radioactive Waste Disposal & Incineration	US Ecology (USE89) Needles Site, CA	7E-01	7E-01
	US Ecology (USE91) Butte, NE	7E-01	6E-01
	SEG (SEG91) Oak Ridge, TN	<7E-03	<3E-04
	Barnwell Site Aiken, SC	Emissions not measurable above background	
	Beatty Site Beatty, NV	Emissions not measurable above background	
	Hanford Site Richland, WA	Emissions not measurable above background	

1. Results are for residents unless otherwise stated. All values are rounded to the nearest whole number.

2. Nonresident: COMPLY result multiplied by a factor of 0.3 for people in businesses or offices.

4. Results of Random Survey of Licensees

4.1 PURPOSE OF THE RANDOM SURVEY

In the previous radionuclide NESHAPs rulemaking for the source category of the NRC-licensed facilities other than nuclear power reactors, the Administrator found that current levels of emissions were acceptable. The dose and risk assessments the Administrator used in making his decision were based on evaluations of facilities believed to have the greatest potential emissions, i.e., they were the worst case facilities (see Chapter 3). However, limitations in EPA's knowledge about the thousands of facilities included in this source category led to some uncertainty as to whether the facilities evaluated bounded the maximum doses and risks.

The purpose of the random survey is to provide additional confidence that the facilities evaluated previously by EPA, and presumed to represent the "worst cases" in terms of MIR, actually do represent the upper-bound of the doses caused by the NRC-licensed facilities. Given the number of facilities in the sample (approximately 350), the probability statement that the highest estimated dose observed in the sample is greater than or equal to the 99th percentile dose for the entire population can be made at the 95 percent confidence level.

This chapter evaluates the radiological impacts of NRC's programs, using actual or estimated data reported by all sampled operating facilities. It presents a current "snapshot" in time of the doses caused by the normal operation of the NRC-licensed facilities.

In making its evaluation, EPA chose the computer code COMPLY to estimate doses. COMPLY was chosen because, for many of the situations being assessed, COMPLY's dispersion model is more appropriate than available alternatives, including the CAP-88 codes. In making dose evaluations, the procedures set forth in EPA89a were followed with two adjustments. First, the default release fraction of 1 was not used to estimate Xe-133 emissions from radiopharmaceutical manufacturers and nuclear pharmacies. Second, for sites where the location of the receptor was a school or office rather than a residence, an occupancy factor was applied. These adjustments are discussed more fully in Section 4.2.

4.2 METHODS FOR SELECTING THE RANDOM SAMPLE AND DATA REQUIREMENTS

4.2.1 Selection Criteria

Because the facilities of interest number in the thousands, it was not feasible to evaluate all emissions and doses. Accordingly, the only way to increase the certainty that the maximum doses observed in the Designated Survey of facilities actually represent the upper bound is by using statistically significant data obtained from a sample of all facilities. The statistical approach is based on a random sample of facilities selected from lists of licensed facilities provided to EPA by NRC and the Agreement States. Facilities with no potential for airborne emissions during routine operations, i.e., those using radioactive sources only in a sealed form (sealed sources), such as well-logging, were excluded from the Random Survey. The only other facilities excluded from the survey were fuel cycle facilities licensed by NRC.

4.2.2 Data Requirements

In order to make the dose estimates, site-specific data were required from users of unsealed sources of radioactivity. Questionnaires were sent to a random sample of facilities using radioactive materials to obtain the release rates and other necessary parameters from those using unsealed sources. The selected assurance level of 95 percent requires a sample of dose estimates for approximately 300 facilities to infer the dose below which 99 percent of all licensed facilities lie.

Table 4-1 summarizes the sample selection process and responses. The database available for sampling, compiled from NRC- and state-supplied data, included approximately 12,000 facilities. State-supplied data were generated in response to an EPA request for information sent to each Agreement State. The input obtained for the database includes licensed facilities using both sealed and unsealed sources.

The database distinguished between those facilities licensed directly by NRC (strata one) and those licensed through Agreement States (strata two). The relative frequency of facilities using only unsealed sources differs in these two strata (i.e., population of facilities) due to the differing sources of information on licensees in these strata. Initial sampling of these strata permitted estimation of the relative proportion of unsealed source sites in each

Table 4-1. Summary of Random Survey responses.

		NRC	Agreement States	Total
1.	Number of Facilities in Database	6,600	5,700	12,300
2.	Number of Facilities Surveyed (percent of item 1 above)	360 5.5%	310 5.4%	670 5.4%
3.	Number of Unsealed Source Sites (percent of item 2 above)	170 47%	200 65%	370 55%
4.	Estimated Number of Unsealed Source Sites in Population (percent of total)	2,800 45%	3,400 55%	6,200
5.	Number of Sites Submitting Questionnaire Data for COMPLY (percent of total)	169 46%	198 54%	367
6.	Estimated Sampling Frequency of Unsealed Source Sites[a] (item 5 as percent of item 4)	6.2%	5.9%	6.0%
a.	The agreement of the three percentages in item 6 indicates a nearly proportional sample of NRC and Agreement State unsealed source sites.			

strata. Sampling frequencies for selection from the two strata were adjusted slightly to yield a targeted number of unsealed source sites in each strata. From the entire sample, it is estimated that 47 percent of the NRC-licensed facilities and 65 percent of the facilities licensed by Agreement States used unsealed sources. Selected facilities using other than just sealed sources were asked to complete the questionnaire. The questionnaire is presented in Appendix G.

Based on the sample proportions of unsealed source sites in each strata, it is estimated that there are approximately 6,200 facilities using only unsealed sources.

The final result of the sample selection procedure was a nearly proportional representation (approximately 6 percent) of the estimated number of unsealed source sites in each strata. Information was obtained from 367 sites, with 169 from the NRC strata and 198 from the Agreement State strata. These sample sizes result in approximately equal sampling weights for sample facilities in each strata. Due to the equal weighting of the selected sample facilities, the sample is considered to be "self-weighting" in the statistical analysis below.

Some or all of the following information was obtained through EPA's questionnaires:

- The emission rate or annual usage of each radionuclide to calculate the annual amount released;
- The size of the building (maximum length, width, and height), which influences the dispersion pattern;
- The distance and direction to the receptor (both a resident and the closest office, school, business, or classroom) and the distances to the locations where vegetables, milk, and meat are produced (farms, not restaurants or stores). These factors influence the dose received through various pathways; and
- Information regarding the height, diameter, and flow rate of the stacks or vents from which the radioactivity is released.

In addition, data regarding the frequency the wind blows from a given direction and its average speed for each of 16 sectors (e.g., N, NNE, NE, ...) were obtained from the National Oceanic and Atmospheric Administration (NOAA). This is called a wind rose and, together with the dimensions of the building from which the radionuclides are released, is used to determine the radionuclide concentrations in air at the receptor locations.

The cases studied were based upon specific data and assumptions. The emission rates were either the measured values supplied by the facility on the survey form or were based upon the actual amount of radioactive material used at the facility as indicated on the survey form. The product of the actual amount of each radionuclide used during a one-year period and a release fraction gives the estimated release rate. The release fractions used were those given in "A Guide for Determining Compliance with the Clean Air Act Standards for Radionuclide Emissions from NRC-Licensed and Non-DOE Federal Facilities" (EPA89a). If the respondent indicated that effluent controls (HEPA filters, charcoal filters, etc.) were used, then the emissions estimated using the release fractions were reduced by the factors given in EPA89b for the various effluent controls. The only exception to this was the use of a release fraction of 0.01 (1.0 percent) for xenon at nuclear pharmacies. The Food and Drug Administration limits the leakage of xenon to 0.5 percent per day (Mu91).

The meteorological information from the closest location having terrain similar to the site was used. Data from 453 weather stations in the United States were available to generate wind roses to use in COMPLY (NOAA90).

The closest receptor was located at the distance and direction indicated by the survey form. If the closest receptor was a resident not living in the building releasing the radionuclides, the receptor's source of vegetables was taken to be at the location of the receptor's home. The receptor's source of milk and meat was located at the closer of either the distance indicated by the survey form or a default value of 2,000 m. If the closest receptor was in an office, school, or business, or if the receptor lived in the building where the release occurred, the sources of vegetables, milk, and meat were taken to be the closer of either the distance given by the survey form or 2,000 m.

The building dimensions and stack parameters used were those supplied by the survey form. If there were no offices or residences in the building from which the release occurs, then COMPLY does not need stack information unless there is a tall stack (greater than 2.5 times the building height). If the stack is less than 2.5 times the building height, COMPLY treats the release as a ground-level release and applies modified Gaussian plume or empirical models to estimate dispersion.

If the closest receptor was in an office, school, or business (as opposed to a residence), an occupancy factor of 0.3 was applied. The value of 0.3 is based upon 10 hours per day, 5 days per week, 52 weeks per year (10x5x52/8760=0.3). If the closest receptor was in a classroom at a college or university, an occupancy factor of 0.1 was applied. The value of 0.1 is based upon 20 class hours per week, 45 weeks per year (20x45/8760=0.1).

The reported dose is the larger of the calculated dose to the closest resident, 0.3 times the calculated dose to someone in the nearest office, school, or business, or 0.1 times the calculated dose received in a college classroom.

4.3 METHODS FOR EVALUATING DATA

Radioactive releases from a facility may contribute to radiation exposure through several external and internal exposure pathways. External exposures may result from direct cloud immersion or from radionuclides deposited on the ground. Internal exposure may result from inhalation of airborne radioactivity or from ingestion of contaminated food products. The magnitude of public exposure from a facility is largely determined by the quantity of specific radionuclides contained in the airborne emissions and by the atmospheric dispersion and deposition processes.

Computer codes are commonly used to model dispersion and deposition processes that determine human exposure. EPA has developed the COMPLY computer program to estimate doses from radionuclide emissions to the air. The following documents provide more information about COMPLY:

- EPA 520/1-89-001, "BID Procedures Approved for Demonstrating Compliance with 40 CFR Part 61, Subpart I"
- EPA 520/1-89-002, "A Guide for Determining Compliance with the Clean Air Act Standards for Radionuclide Emissions from NRC-Licensed and Non-DOE Federal Facilities"
- EPA 520/1-89-003, "User's Guide for the COMPLY Code"

COMPLY is an air-dispersion code. That is, it takes estimated or measured airborne effluent release rates, calculates the amount by which the radioactivity is diluted as it is carried by the wind, and estimates air, ground, plant, and animal radionuclide concentrations at various distances from the release point. From these concentrations, COMPLY calculates the radiation dose resulting from immersion, ingestion, inhalation, and exposure to ground contaminated by deposition of airborne radioactivity.

COMPLY has several levels of complexity. As the complexity increases, the estimates become more realistic, and more information is required to run the code. All cases in the random survey of licensees were run using the most realistic level (Level 4).

4.4 RAW RESULTS OF THE SURVEY

4.4.1 Results

NRC's programs have been evaluated based on the calculated maximum individual doses resulting from the operation of licensed facilities. Maximum individual doses were calculated using COMPLY with input from EPA's questionnaires. The highest estimated dose is 8 mrem/yr for all nuclides and 0.67 mrem/yr for iodine. Table 4-2 presents the number of facilities having doses in various ranges. Seven facilities have doses above 1 mrem/yr, and none has doses above 10 mrem/yr. These doses are below the limits established by the NESHAP. Section 4.5 contains a statistical analysis of these results.

Table 4-2. Number of facilities having doses in various ranges.

Maximum Individual Effective Dose Equivalent (mrem/yr)	From All Nuclides	From Radioiodine
1E-13 to 1E-12	0	1
1E-12 to 1E-11	0	2
1E-11 to 1E-10	3	7
1E-10 to 1E-09	2	24
1E-09 to 1E-08	4	18
1E-08 to 1E-07	7	23
1E-07 to 1E-06	16	30
1E-06 to 1E-05	29	47
1E-05 to 1E-04	56	33
1E-04 to 1E-03	79	36
1E-03 to 1E-02	82	32
1E-02 to 1E-01	66	28
1E-01 to 1.0	16	9
1.0 to 10	7	0
> 10	0	0
Total	367	290

4.4.2 Translation from Dose to Risk

The EPA standard for NRC licensees under Subpart I is in terms of effective dose equivalent, a system of dose estimation recommended by the International Commission on Radiation Protection (ICRP). EPA adopted this system because it is simple, related to risk, and widely accepted by leading national and international advisory bodies.

EPA's past risk models differ slightly from those underlying the ICRP recommendations, primarily due to advances in the field of radiation risk since the ICRP recommendations were published. As a result, the risks calculated by EPA are not strictly proportional to the ede derived using the ICRP quality factors and organ weighting factors.

While the risk methodology underlying the ICRP ede differs from that used by EPA in the past, EPA believes that 3 mrem/yr ede is approximately equal to a lifetime individual risk of 1 in 10,000.

4.4.3 Assumptions

Because assumptions can have a significant effect on the outcome of a study, those made in running the COMPLY code are discussed in greater depth in Appendix H.

4.4.4 Population Dose Estimates

As discussed in Section 1.2, the multi-factor approach adopted by EPA for determining whether the emissions from a given source category are safe with an ample margin considers both the total incidence of health effects and the distribution of the risk across all individuals in the exposed populations in conjunction with the risk to the maximally exposed individuals. In the BID supporting the 1989 rulemaking (EPA89), the fatal cancer incidence for the NRC-licensed source category was given as 0.2 deaths/yr, and 99 percent of the exposed population (the entire U.S. population, assumed to be 240 million) was estimated to be at a risk level of less than 1E-06. The data obtained from the Random Survey have been examined to determine whether they are consistent with these population risk estimates.

As indicated in Table 4-2, no facilities were estimated to produce doses in excess of 10 mrem/yr. This would indicate that very few, if any, individuals have been exposed to a lifetime risk substantially in excess of 1E-04, as discussed below.

Table 4-2 also reveals that several facilities have produced doses in excess of approximately 0.01 to 0.1 mrem/yr, which is associated with a lifetime risk of cancer on the order of 1E-06. Using 0.03 mrem/yr as the dose associated with 1E-06 lifetime risk of cancer, 52 of the 367 facilities evaluated may have emissions associated with risks in excess of 1E-06.

The population dose was estimated for each of the facilities in the sample where a person received a dose greater than 0.03 mrem/yr. The calculation was carried out by finding the distances at which the sector-averaged doses fell in the ranges of 0.03 to 0.3,

0.3 to 3.0, and 3.0 to 10 mrem/yr. The numbers of people in the annuli defined by these distances were estimated using Census Bureau data (CB88). The number of people at the various levels of exposure is shown in Table 4-3.

Table 4-3. Population dose estimates.

Dose (mrem/yr)	Approximate Risk	Estimated Number of People in Sample of 367	Estimated Number of People for 6,200 Facilities
0.03 to 0.3	1E-06 to 1E-05	2,000	34,000
0.3 to 3	1E-05 to 1E-04	89	1,500
3 to 10	1E-04 to 1E-03	1	17

The estimated number of people at each level of exposure for the 6,200 facilities is 6,200/367 (= 17) times the number in the sample of 367. The estimated number of cancer deaths is about 0.3 per year, and more than 99 percent of the population is at a risk level of less than 1E-06. These estimates are consistent with the estimates in the 1989 BID (EPA89).

4.5 STATISTICAL INTERPRETATION OF THE RESULTS

The principal objective of the Random Survey design was to answer the following question: "What is the value of X such that, with at least 95 percent assurance, the 99th percentile of the distribution of doses from these facilities does not exceed X mrem/yr, where X mrem/yr is the highest dose estimated for all the facilities in the sample?" A second objective was to estimate other percentiles of dose based on the statistics derived from a fitted dose distribution. Finally, models fitted to the sample distribution of exposures permit extrapolation of the fitted curves out to 10 mrem/yr and beyond.

Previous analyses of the maximum dose to the public from NRC-licensed facilities other than nuclear power reactors relied on the analyst's judgment in selecting the facilities most likely to have high exposures. This current analysis was designed to reduce the uncertainty inherent in these judgments by using random sampling methods to provide additional information about the population distribution of doses to maximally exposed individuals at these sites.

Extrapolating the results of this study to the entire population of the NRC-licensed facilities other than nuclear power reactors involves three assumptions:

1. All facility estimates are based on running the COMPLY code and thus depend both on collecting appropriate data on emissions and nearby individuals from each facility and on the ability of the code and its user to model the maximum individual exposure based on these data. All the data must be submitted, interpreted, and used in a similar manner.

2. Non-parametric estimates of population parameters, such as using the sample maximum to provide an upper bound on the 99th percentile of the population distribution or extrapolating sample percentiles to the population, depend on the representativeness of the selected sample.

3. Parametric estimates of the population parameters, such as the arithmetic or geometric mean, depend on assumptions concerning the specific mathematical form of the population distribution. Parametric estimates for the upper percentiles of the population distribution are least robust to departures from the assumed probability distribution.

The sources of uncertainty associated with these three assumptions are difficult to quantify.

The maximum individual dose estimates cited in Table 4-2 from all nuclides and from radioiodine only are summarized in Tables 4-4 and 4-5, respectively. Table 4-4 provides the range, median, arithmetic and geometric mean, as well as distribution percentiles of the effective dose equivalents for the 367 facilities in the Random Survey that use unsealed sources. Table 4-4 summarizes results for doses from all radionuclide sources, and Table 4-5 summarizes radioiodine doses for the 290 sample facilities using radioiodines.

Sample doses in Part A of Table 4-4 range from 2.3E-11 mrem/yr up to 8 mrem/yr, with a median dose of 6.9E-04 mrem/yr. The geometric mean is below the median, at 4.4E-04 mrem/yr, while the arithmetic mean is significantly higher than the median and geometric mean, at 9.1E-02 mrem/yr.

Examination of the estimated percentiles of the dose distribution in Part B of Table 4-4 supports the following conclusions, based on the use of the sample distribution percentiles to provide unbiased point estimates of the population percentiles:

Table 4-4. Estimated distribution of maximum individual doses.

A. Selected characteristics of the random sample	
Sample Characteristic	Value
Minimum Dose	2.3E-11 mrem/yr
Geometric Mean	4.4E-04 mrem/yr
Median Dose	6.9E-04 mrem/yr
Arithmetic Mean	9.1E-02 mrem/yr
Maximum Dose	8.0E+00 mrem/yr
Sample Size	367

B. Selected percentiles of the estimated dose distribution			
Sample or Population Percentile	Dose (mrem/yr)	Estimated Number of Facilities at or Exceeding This Dose:	
		In Sample	In Population
10	1.6E-06	331	5,538
20	1.7E-05	294	4,922
30	9.2E-05	257	4,307
40	2.7E-04	220	3,692
50	6.9E-04	184	3,077
60	2.0E-03	147	2,461
70	5.2E-03	110	1,846
80	1.6E-02	73	1,231
90	5.9E-02	36	615
95	2.0E-01	18	308
99.0	3.9E+00	3	62
99.7	8.0E+00	1	18

Table 4-5. Estimated distribution of maximum individual doses for radioiodine.

A. Selected characteristics of the radioiodine dose random sample	
Sample Characteristic	Value
Minimum Dose	1.9E-13
Geometric Mean	6.1E-06
Median Dose	8.1E-06
Arithmetic Mean	1.3E-02
Maximum Dose	6.7E-01
Sample Size	290

B. Selected percentiles of the estimated radioiodine dose distribution			
Sample or Population Percentile	Dose (mrem/yr)	Estimated Number of Facilities at or Exceeding This Dose:	
		In Sample	In Population
10	8.0E-10	261	4,376
20	3.9E-08	232	3,890
30	2.4E-07	203	3,403
40	1.8E-06	174	2,917
50	8.1E-06	145	2,431
60	4.2E-05	116	1,945
70	3.4E-04	87	1,459
80	2.4E-03	58	972
90	2.0E-02	29	486
95	6.0E-02	14	243
99.0	3.9E-01	3	49
99.7	6.7E-01	1	19

1. Doses from all sources at over half of the facilities in the population are below 0.001 mrem/yr.

2. The 95th percentile of the dose due to all sources is estimated to be 0.20 mrem/yr. This dose is exceeded by 18 (approximately 5 percent) of the sample facilities. We estimate that there are approximately 310 facilities in the population exceeding this level of dose.

3. The 99th percentile of the dose due to all sources is estimated to be 3.9 mrem/yr. This dose is exceeded by three (approximately 1 percent) of the sample facilities. We estimate that there are approximately 60 facilities in the population exceeding this dose level.

Each of these point estimates has an associated uncertainty region. The maximum dose at any of the 367 sample facilities is 8 mrem/yr, indicating that there is more than 95 percent assurance that the 99th percentile of the dose distribution for the entire population of facilities is below 8 mrem/yr, regardless of the form of the population distribution (G178). As noted in (3) above, the expected value of the 99th percentile is 3.9 mrem/yr. There is over 95 percent assurance that the true 99th percentile of the population is less than a factor of 2.1 greater than this point estimate.

Sample radioiodine doses in Part A of Table 4-5 range from 1.9E-13 mrem/yr up to 0.67 mrem/yr, with a median dose of 8.1E-06 mrem/yr. The geometric mean is slightly below the median, at 6.1E-06 mrem/yr, while the arithmetic mean is significantly higher than the median and geometric mean, at 1.3E-02 mrem/yr.

Examination of the estimated percentiles of the iodine dose distribution in Part B of Table 4-5 yields the following conclusions based on the use of the sample distribution to provide unbiased point estimates of the population percentiles:

1. Doses at over half of the population of facilities using iodine sources are below 1.0E-05 mrem/yr.

2. The 95th percentile of the dose due to iodine sources is estimated to be 0.06 mrem/yr. This dose is exceeded by 14 (approximately 5 percent) of the sample facilities using iodine sources. We estimate that there may be approximately 250 facilities in the population exceeding this level of dose.

3. The 99th percentile of the dose due to iodine sources is estimated to be approximately 0.4 mrem/yr. This dose is exceeded by three (approximately 1 percent) of the sample facilities using iodine. We estimate that there may be approximately 50 facilities in the population exceeding this iodine dose level.

These point estimates of the iodine dose distribution have an associated uncertainty region. The maximum dose at any of the 290 sample facilities using iodine sources is 0.67 mrem/yr, indicating that there is more than 95 percent assurance that the 99th percentile of the iodine dose distribution for the population of facilities using iodine sources is below 0.67 mrem/yr, regardless of the form of the population distribution (Gl78). As noted in (3) above, the expected value of the 99th percentile is 0.4 mrem/yr. There is over 95 percent assurance that the true 99th percentile of the population is less than a factor of 1.7 greater than this point estimate.

In the following discussions, additional information concerning the distribution of maximum individual dose from all sources at all facilities, and for the distribution of maximum individual iodine dose at all facilities using iodine sources, is provided by graphical analysis of the sample distributions. The empirical sample distributions are compared to fitted models from the lognormal distribution and the hybrid lognormal (HLN) distribution.

4.5.1 Frequency Distribution Analysis

The frequency distribution of sample doses for all sources is graphed in Figure 4-1, which also shows a lognormal distribution fitted to the data. The vertical bars on this figure show the histogram (bar graph) of base 10 logarithms of the dose estimates at each site. This histogram of the logarithms of the estimated dose would have the standard normal "bell-curve" shape of the fitted distribution if the underlying population distribution were lognormal. Some depletion in the right tail of the sample distribution is evident above 0.1 mrem/yr; otherwise, the data appear to be approximately lognormally distributed from this perspective. There are no obvious extreme outliers in the sample data.

A similar graph showing the distribution of iodine doses and a fitted lognormal model is presented in Figure 4-2. The lognormal model appears less appropriate in this case. The large "shoulder" in the sample distribution near 0.1 mrem/yr gives way to a sudden depletion in the right tail above 0.1 mrem/yr. As a result, the lognormal curve underestimates the sample distribution in the shoulder region and overestimates the sample distribution in the upper tail.

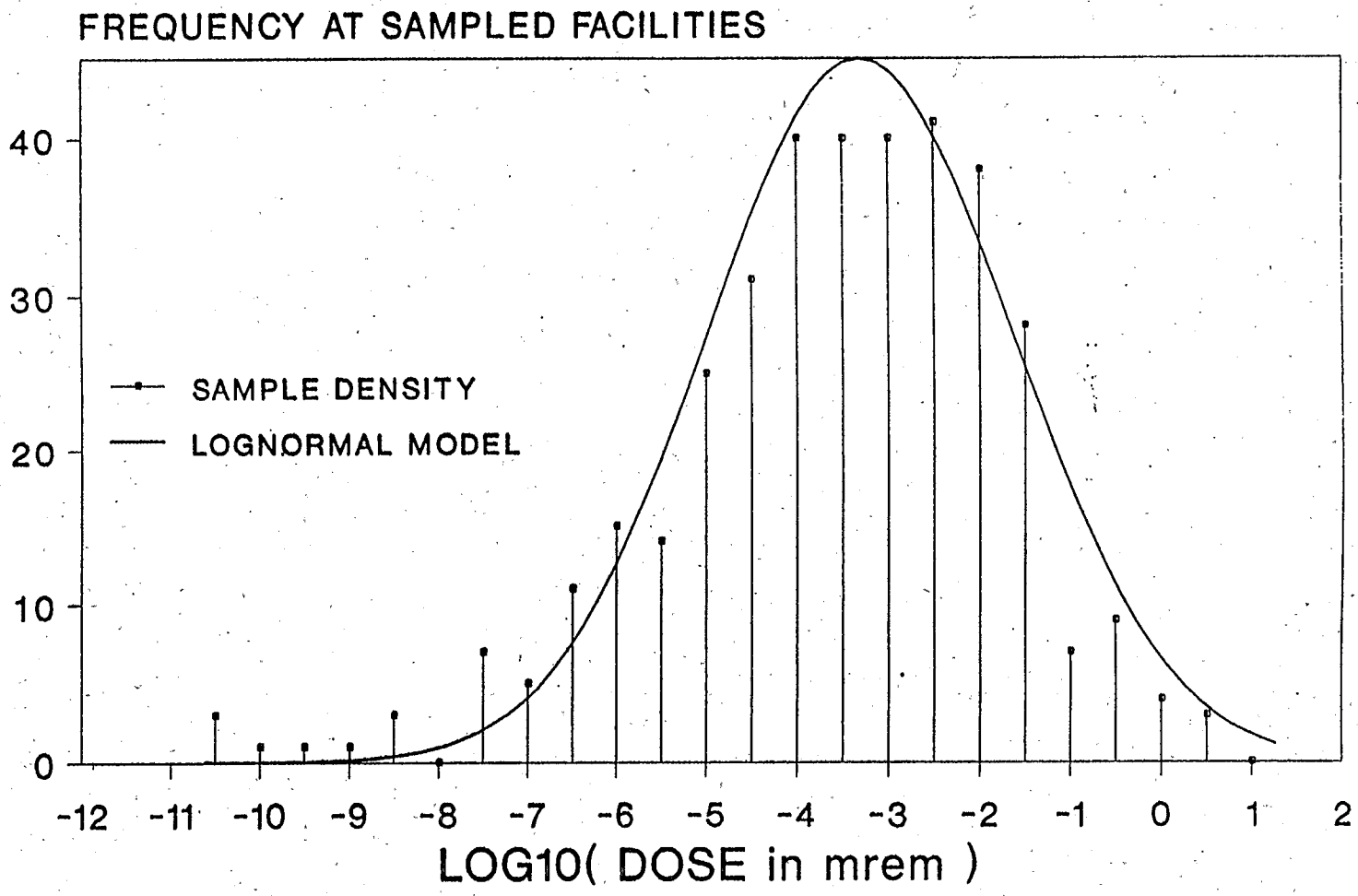

Figure 4-1. Frequency Distribution of Dose for 367 Facilities, with Fitted Model.

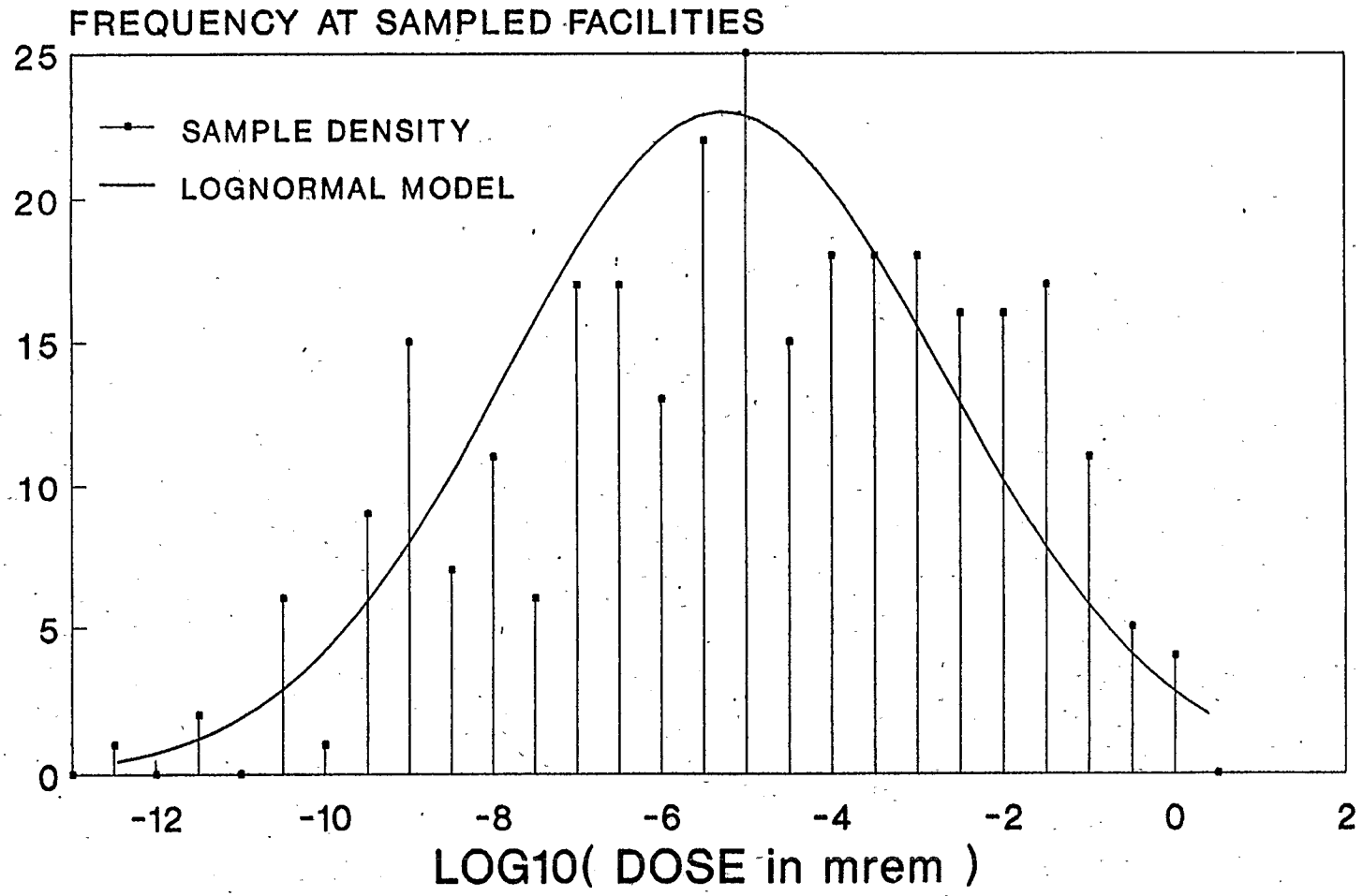

Figure 4-2. Frequency Distribution of Iodine Dose for 290 Facilities, with Fitted Model.

Distributions of the type shown in Figure 4-2 are often encountered in the analysis of dose distributions (EPA84a). The HLN model (EPA84a, Ku81, Ne82) was developed to better fit the depleted upper tail in these distributions. One argument for the HLN distribution is that in the absence of regulations that restrict maximum exposures, the observed distribution of doses would probably be lognormal. Due to the existence of dose-limiting regulations, exposures in the upper tail are "moved down" through active control measures to below the legal threshold, thus depleting the upper tail without changing the general shape of the lower tail. This may lead to a "shoulder" of the type shown in Figure 4-2. In the HLN model, the upper tail is modeled as a normal distribution, and the lower portion of the distribution is modeled as a lognormal. The mixing parameter is defined as "rho" (rho $>$ 0). If the random variable is X, the HLN distribution is predominately a normal distribution above rho$\bullet$X = 1 and predominately a lognormal distribution below rho$\bullet$X = 1; i.e., X = 1/rho is the boundary.

Figure 4-3 compares the fitted lognormal and HLN density functions to the sample iodine dose distribution. The rho parameter was estimated to be 7.7 (see below), indicating that the normal model becomes predominant at approximately 0.1 mrem/yr. The HLN model appears to fit better in the shoulder and upper tail regions; however, there is equal lack of fit in the middle and lower tail regions for both models.

4.5.2 Cumulative Distribution Analysis

Figure 4-4 shows the cumulative sample distribution function and the cumulative distribution of the fitted lognormal distribution for the dose from all sources. The cumulative distribution function plots the percentage of facilities with dose less than or equal to level X. At this scale, the lognormal model appears to fit well. However, in the enlarged view of the upper tail provided by the graph in Figure 4-5, the lognormal model appears to overestimate at the nine highest dose values observed in the sample. Note that the graph in Figure 4-5 does not use a logarithmic scale, which tends to obscure the upper tail region. Also, the vertical axis is defined as the percentage of facilities exceeding a given dose on the X-axis.

Figure 4-6 shows the cumulative sample distribution function, and the cumulative distribution of the fitted lognormal distribution, for the dose from iodine sources. At this scale, the lognormal model appears to fit fairly well, except in the uppermost tail region. In

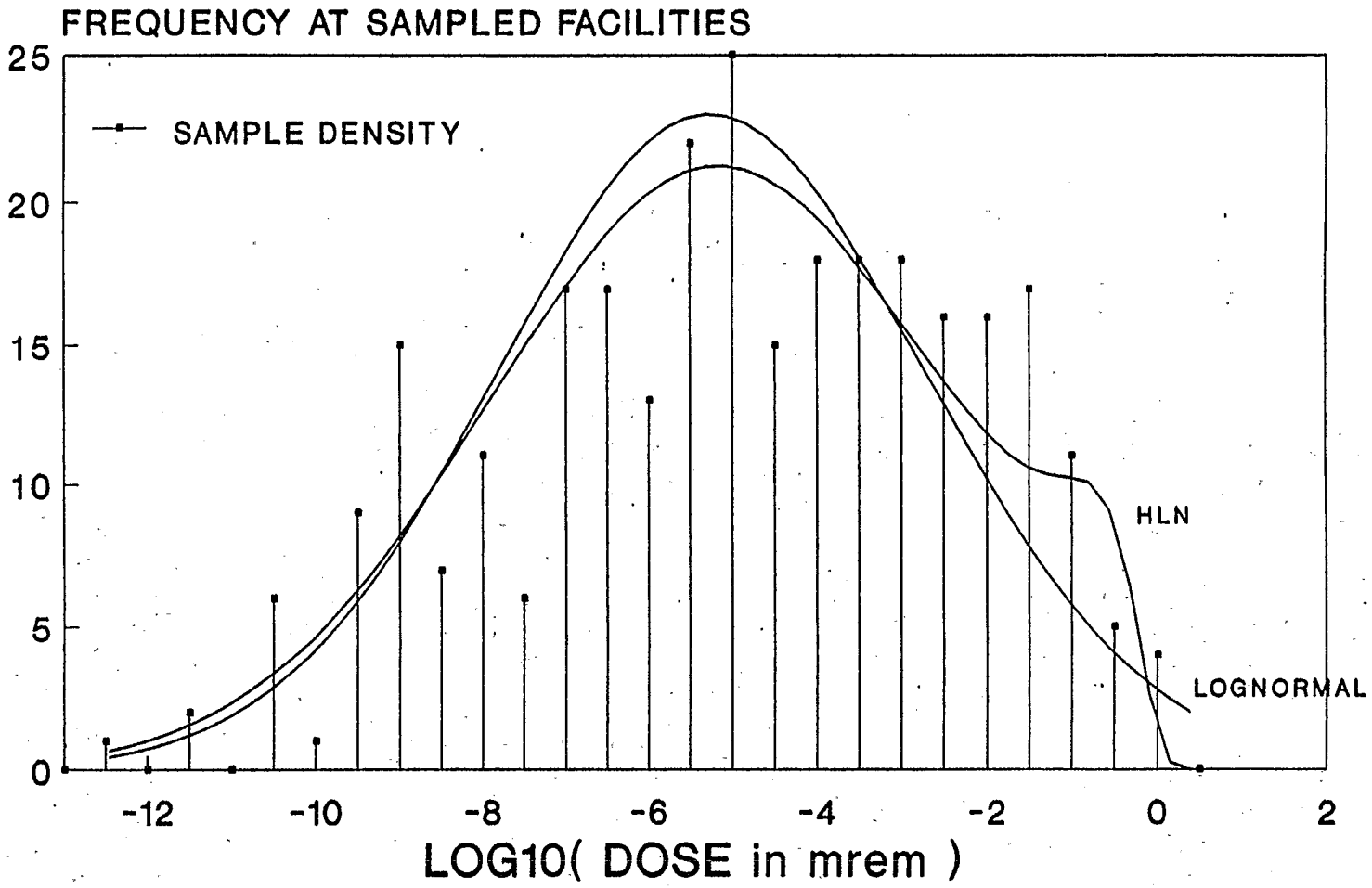

Figure 4-3. Frequency Distribution of Iodine Dose for 290 Facilities, with Fitted Models.

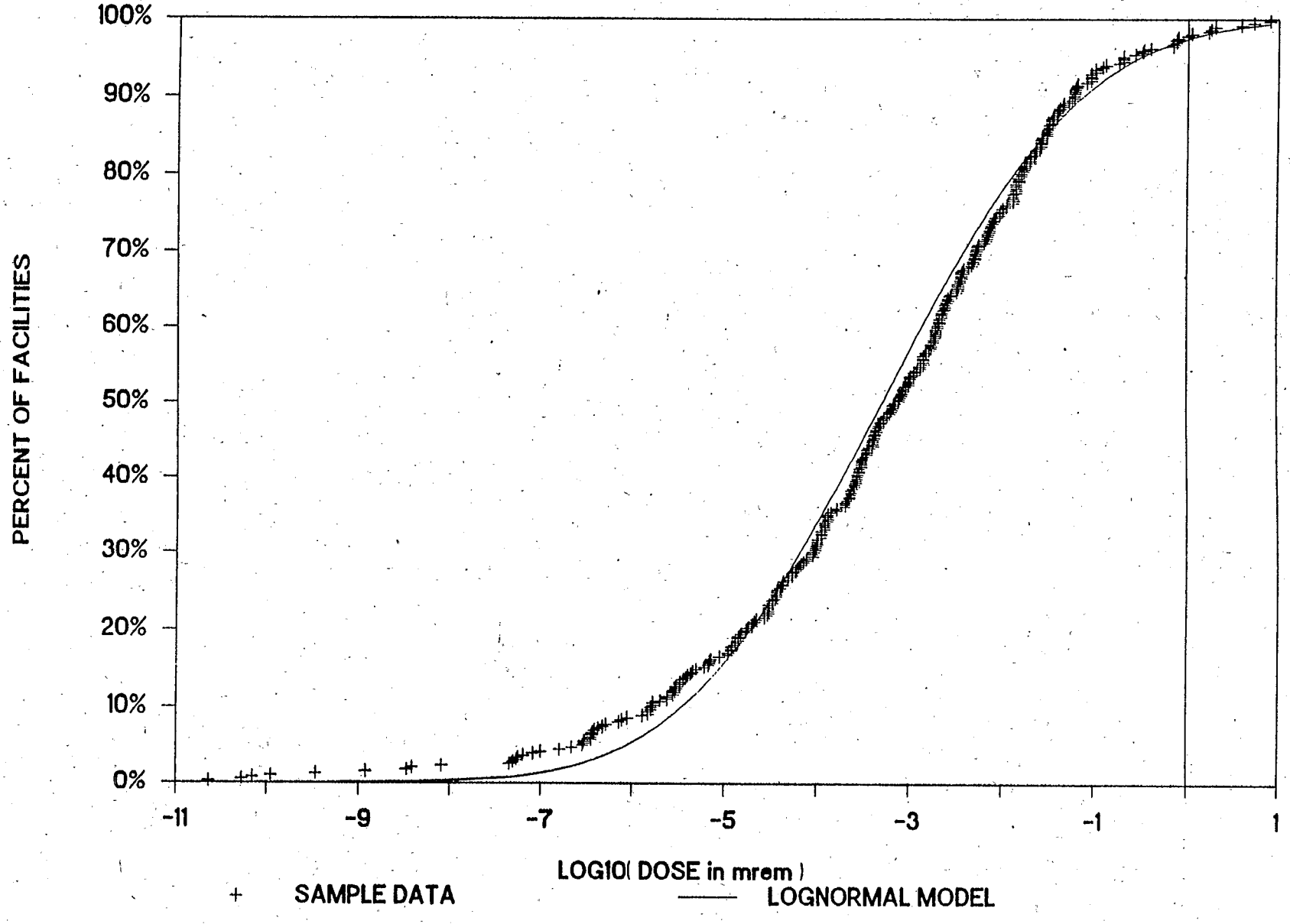

Figure 4-4. Cumulative Dose Distribution with Fitted Lognormal Model.

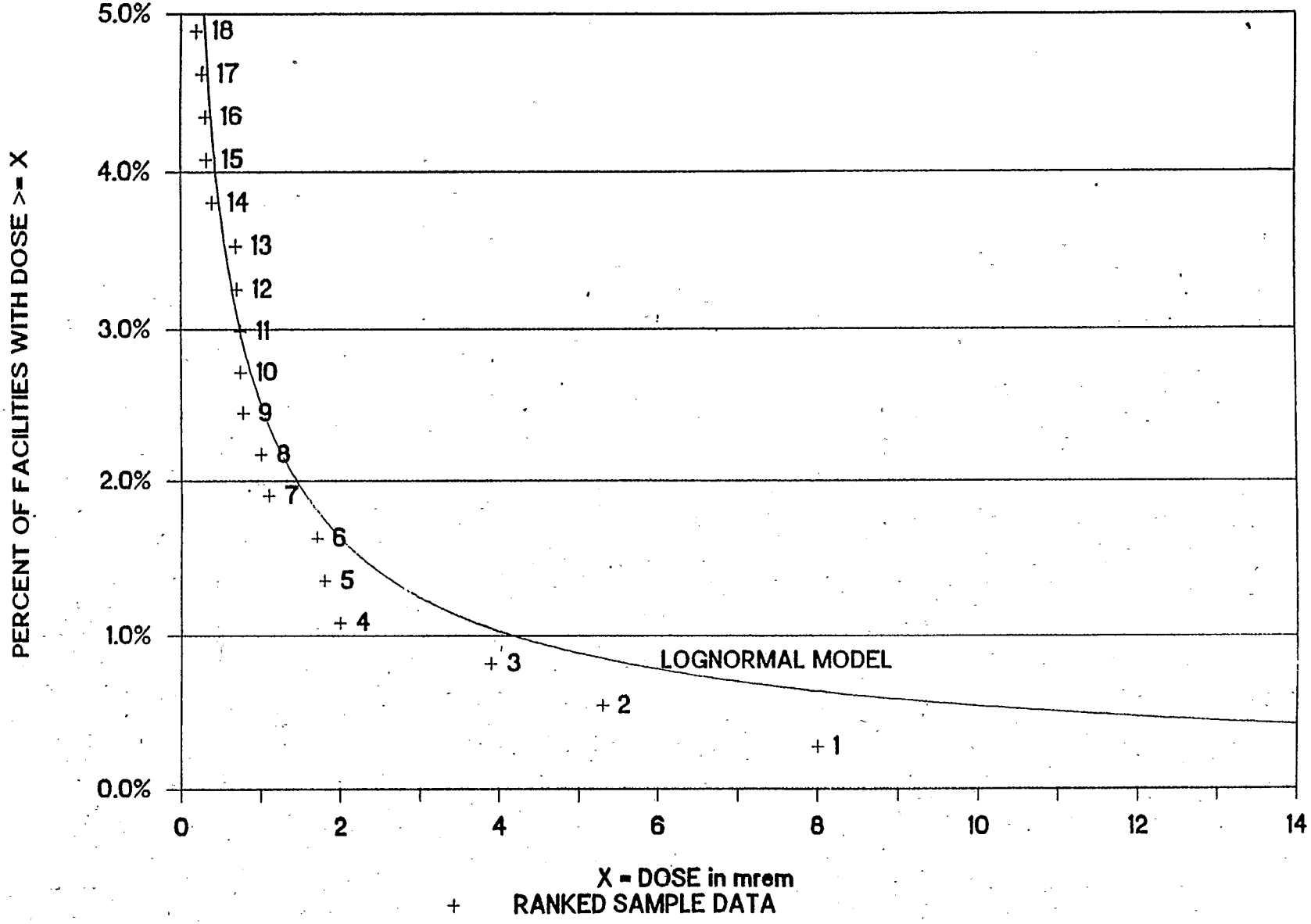

Figure 4-5. Extreme Tail of Sample Distribution with Fitted Lognormal Model.

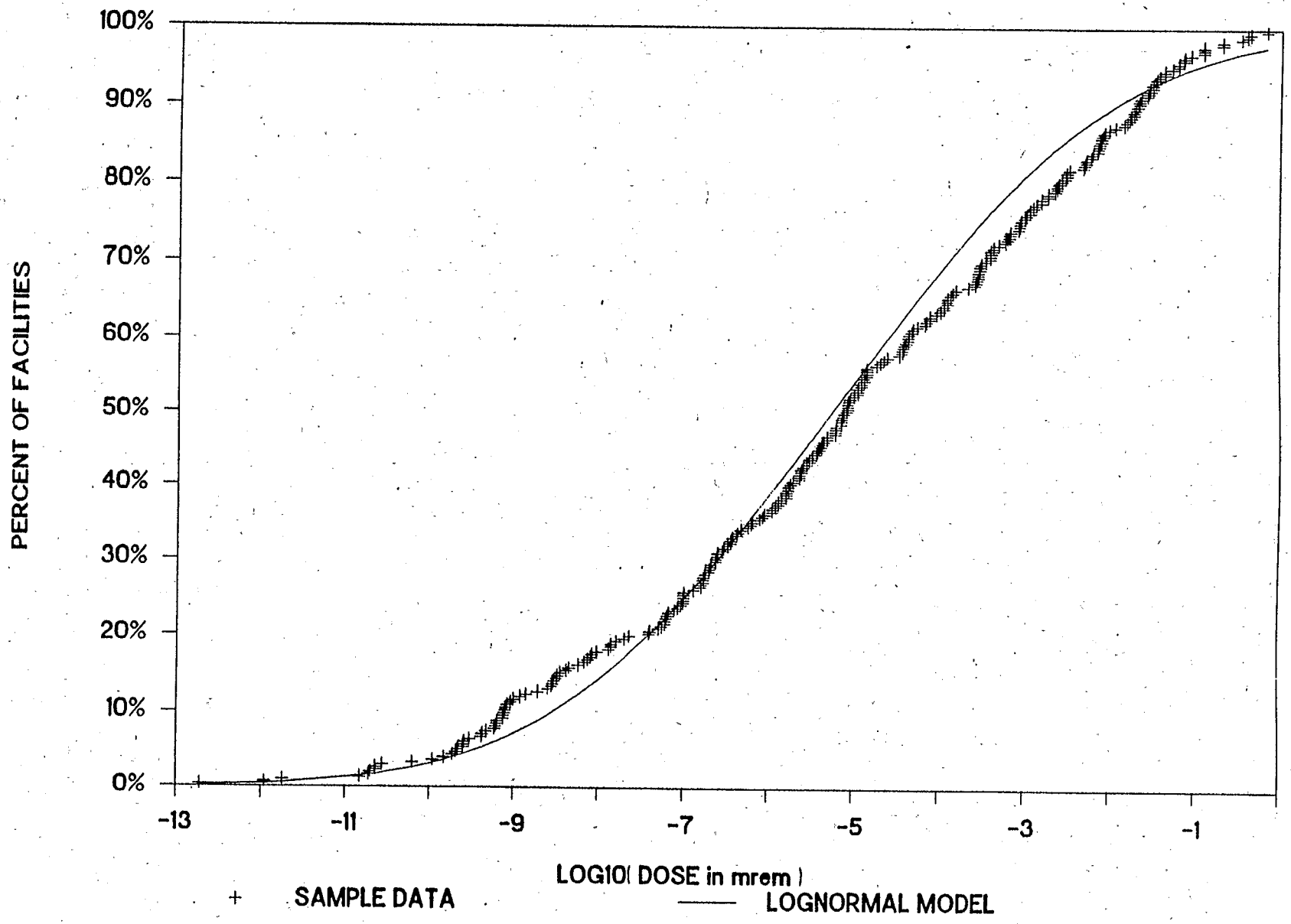

Figure 4-6. Cumulative Iodine Dose Distribution with Fitted Lognormal Model.

the linear scale graph of Figure 4-7, the lognormal model appears seriously to over-estimate the 19 highest iodine dose values observed in the sample. The graphs in Figures 4-4 through 4-7 show that the density function and the cumulative distribution function graphed on a logarithmic scale may obscure the lack-of-fit of the lognormal distribution, particularly in the upper tail. One approach to this problem is the use of a normal probability scale for the vertical axis. The advantage of such transformations is that the data should appear as a straight line when normal probability scales are used, if the selected model is appropriate. Deviation from a straight line, an indication of lack of fit, is easy to observe in graphs of this type.

If a lognormal model is to be fitted, then a plot could be made with the horizontal axis transformed to a natural logarithmic scale (ln X). Alternatively, when fitting the HLN model with mixing parameter rho, the appropriate transformation for the horizontal axis is rho•X + ln(rho•X). Figure 4-8 shows a plot of this type, termed an HLN-probability plot, with the X and Y axes transformed so that data from an HLN distribution would be a straight line. With this transformation, the HLN-fitted line is straight, but not the lognormal line. Note that the upper tail of the sample distribution fits the HLN (straight-line) model slightly better at the highest few data points. The rho parameter for the HLN was estimated to be 0.14, indicating that the normal model is appropriate above approximately 7 mrem/yr, near the highest observed data values. This accounts for the similarity of appearance of the two models over most of the range of observed sample values.

A similar plot for the radioiodine dose distribution is shown in Figure 4-9. In this figure, the poor fit of the lognormal model in the upper tail is very evident. Again the data appear to form a straight line, indicating that the HLN model is appropriate. The rho parameter for the HLN was estimated to be 7.7, indicating that the normal model isappropriate above 0.1 mrem/yr. In this case, the transition to normality occurs well within the range of the observed sample data.

Figure 4-10 compares the fitted lognormal and HLN cumulative distribution functions to the sample dose distribution for dose from all nuclides. In this graph, the distribution for sample doses from all nuclides appears to fit equally well to the two models, and the two models are barely distinguishable. Figure 4-11 shows an enlargement of the extreme right tail of this distribution, with the data for the 18 highest values denoted by "+'s." The fitted HLN model passes nearer the highest 10 data points, which demonstrates that the fit of the

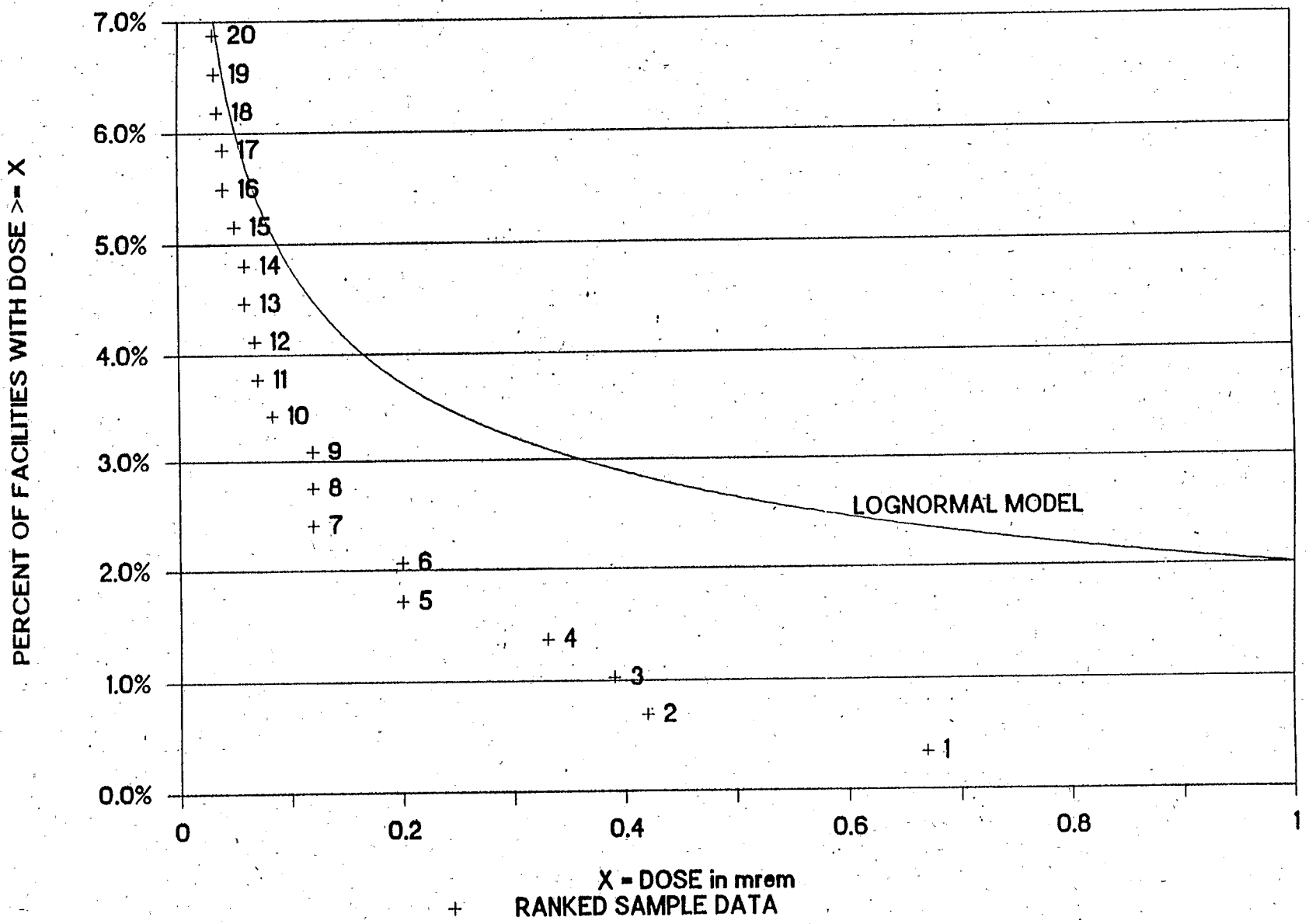

Figure 4-7. Extreme Tail of Iodine Distribution with Fitted Lognormal Model.

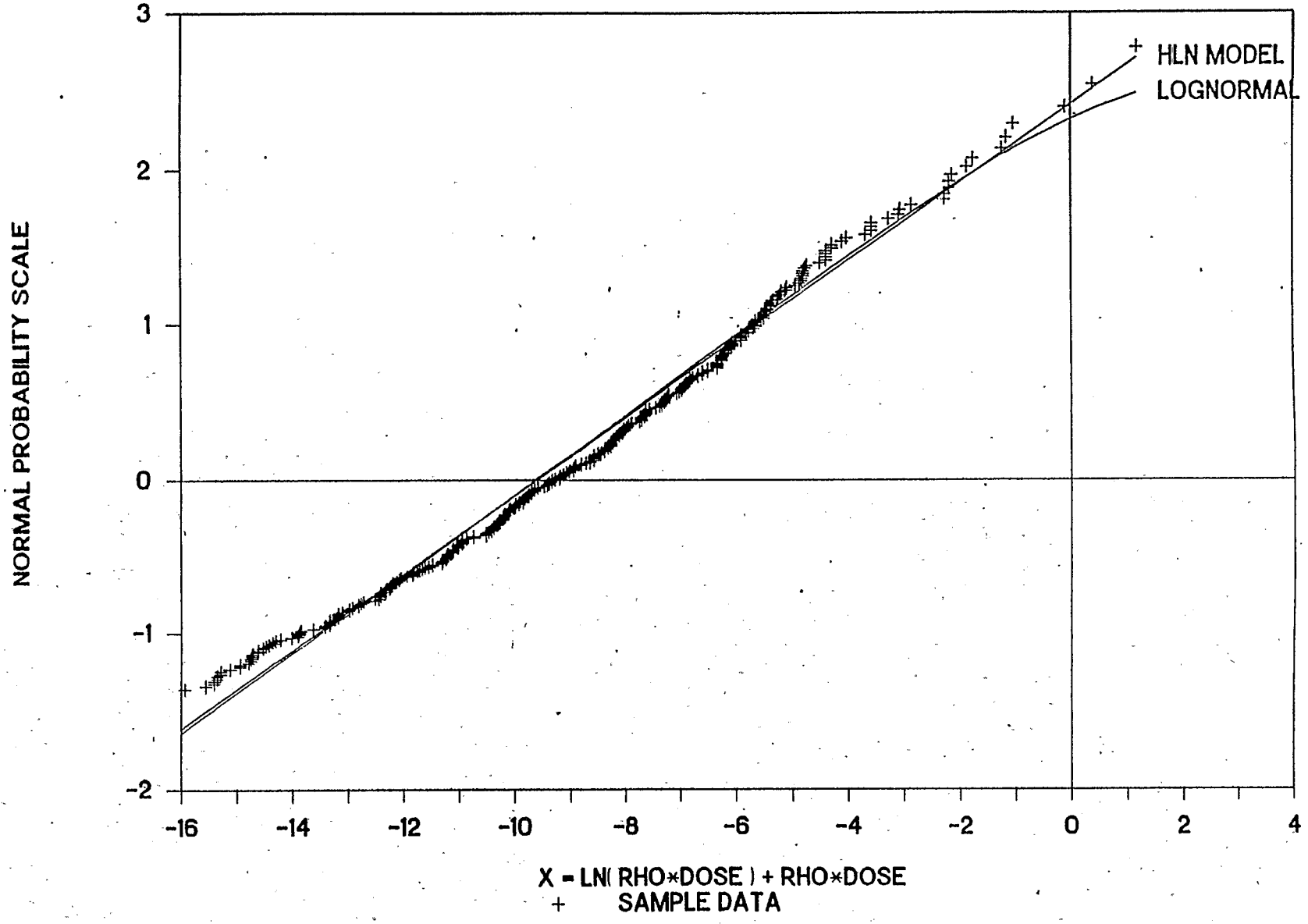

Figure 4-8. HLN-Probability Plot with Rho=0.14 with Fitted Lognormal and HLN Models.

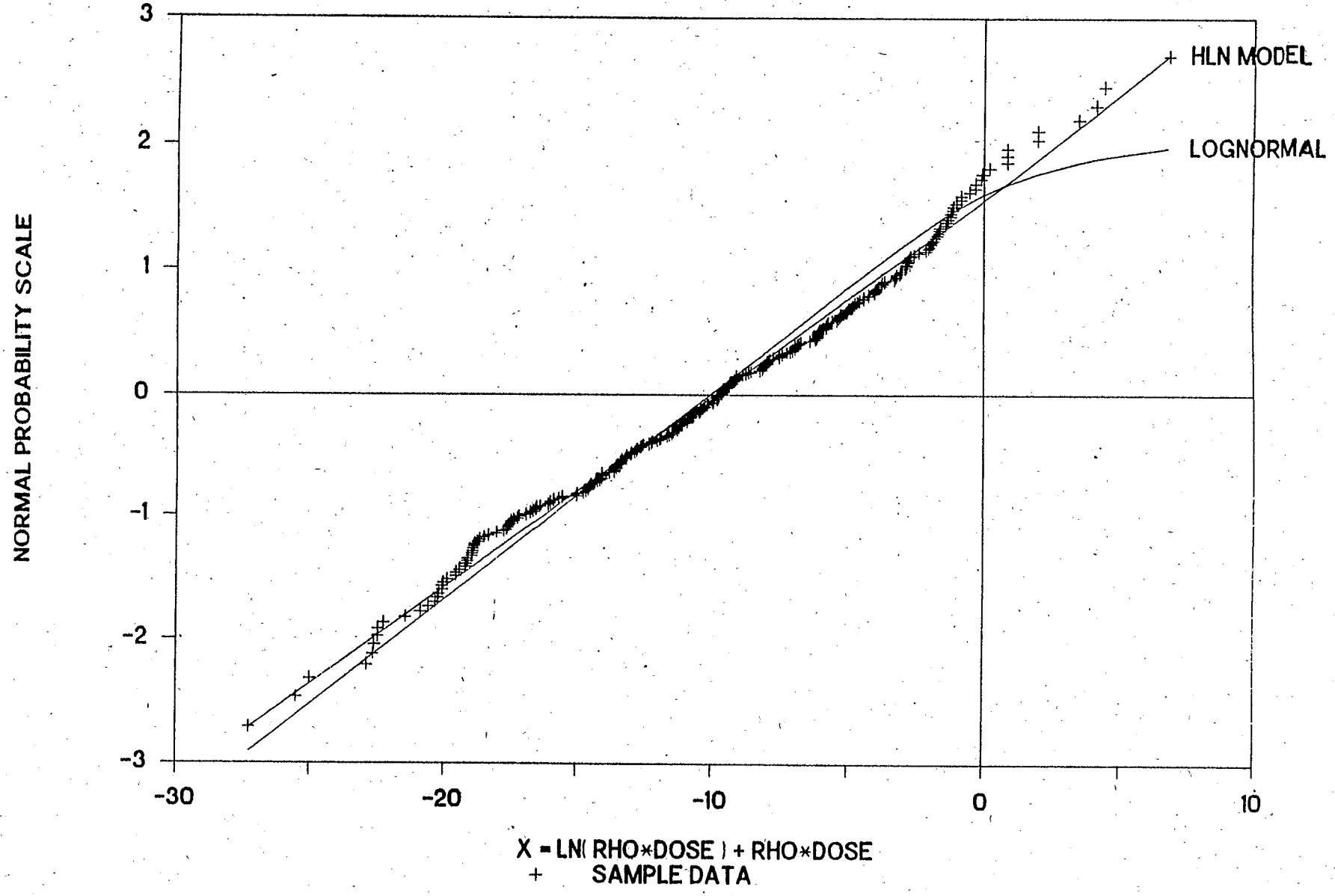

Figure 4-9. HLN-Probability Plot with Rhr=7.7 with Lognormal and HLN Model for Iodine.

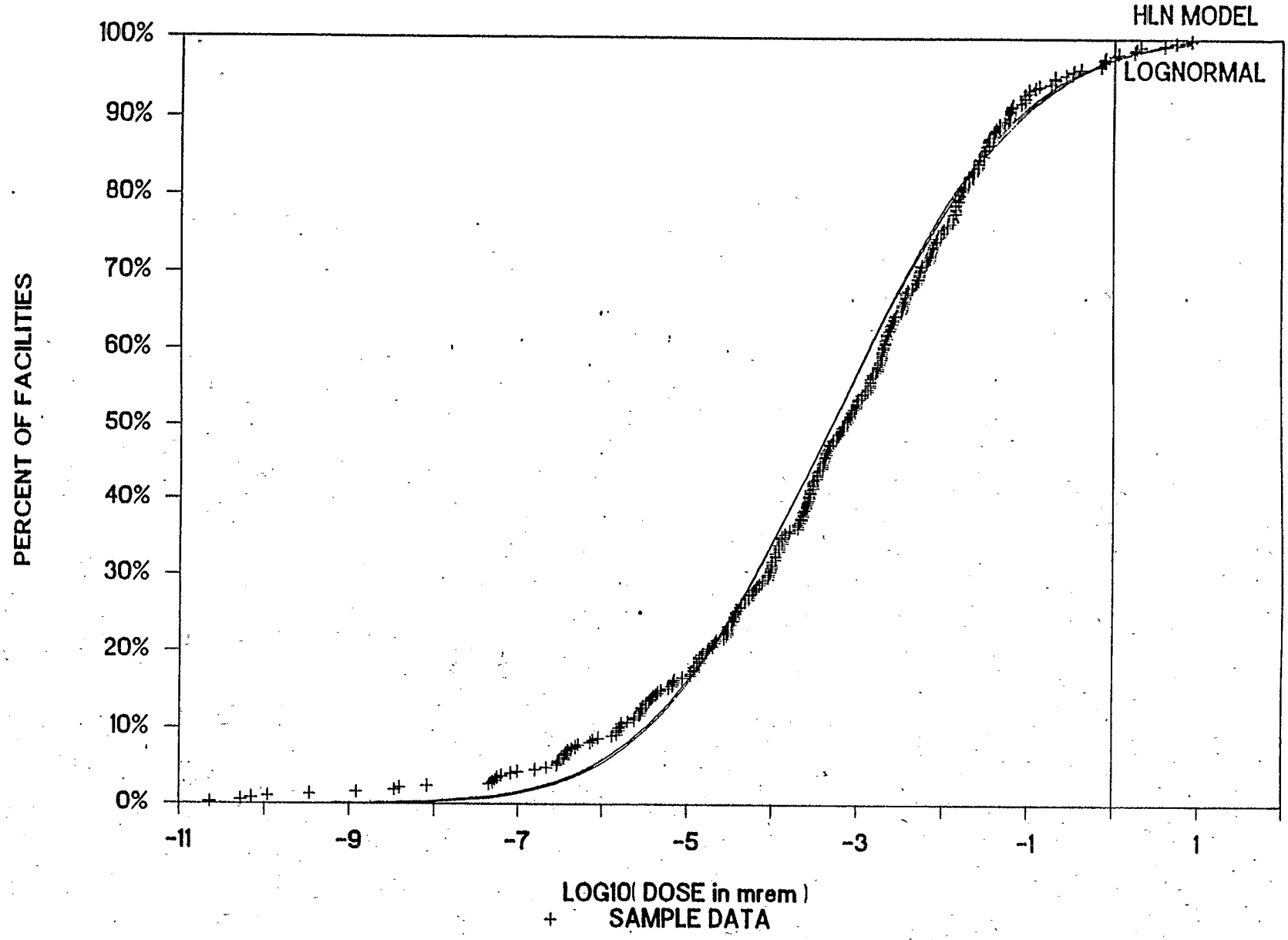

Figure 4-10. Cumulative Dose Distribution with Fitted Lognormal and HLN Models.

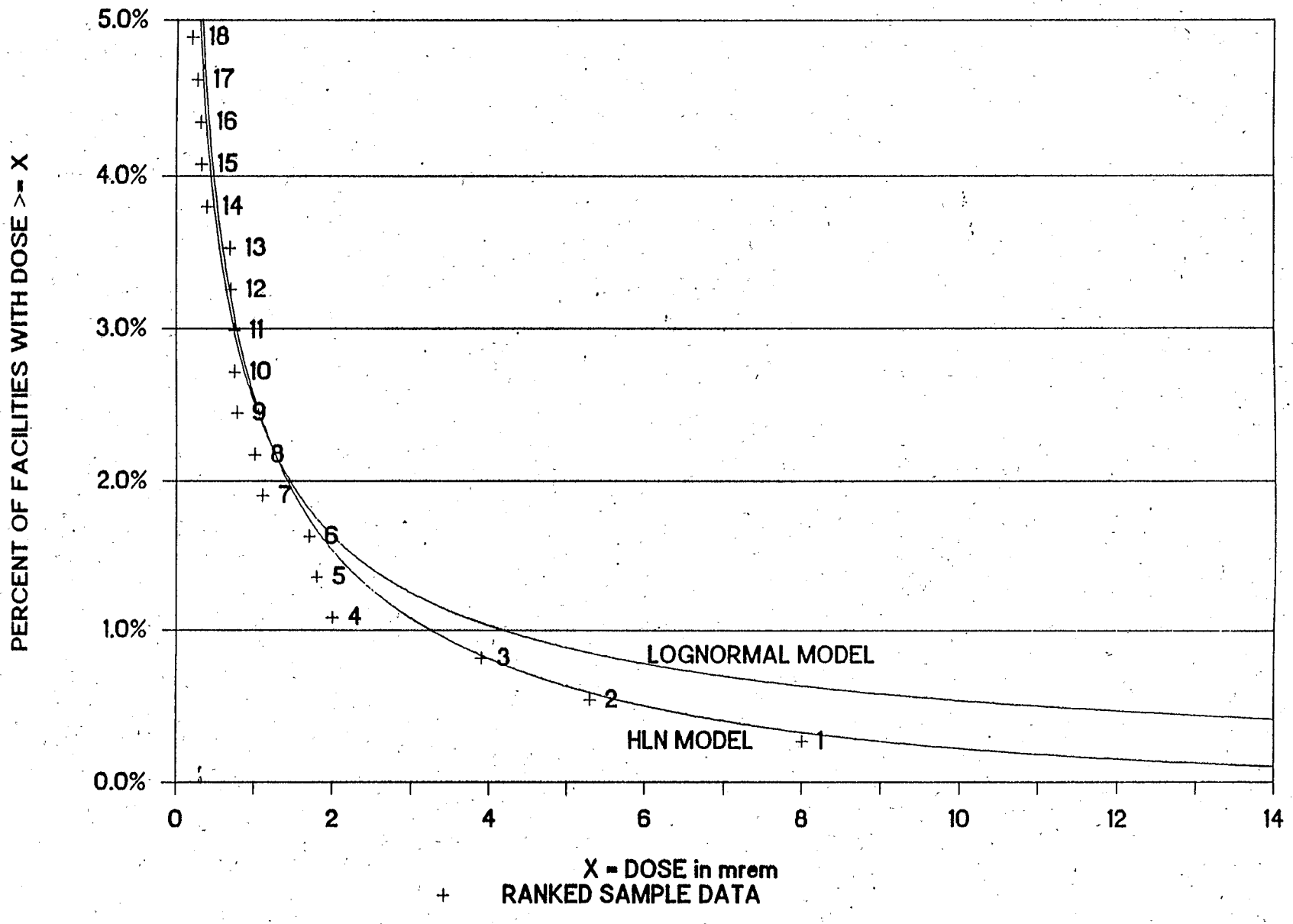

Figure 4-11. Extreme Tail of Sample Distribution with Fitted Lognormal and HLN Models.

HLN distribution is better in the extreme right tail of the sample distribution. The HLN model departs from the lognormal model at approximately 1 mrem/yr and then approaches zero more quickly. Alternatively, the lognormal model decreases slowly out to 10 mrem/yr and beyond. The cumulative distribution of radioiodine doses in the sample and the fitted lognormal and HLN models are shown in Figure 4-12. The distribution of sample radioiodine doses appears to fit somewhat better to the HLN line. Figure 4-13 shows an enlargement of the extreme right tail, with the data for the 20 highest values denoted by "+'s." The fitted HLN model line is close to the highest four values, demonstrating that the fit of the HLN distribution is much better in the extreme right tail of the sample radioiodine distribution. The HLN model departs from the lognormal model at approximately 0.1 mrem/yr, and then approaches zero more quickly. Alternatively, the lognormal model decreases slowly out to 1 mrem/yr and beyond.

The graphs in Figures 4-11 and 4-13 show the fitted lognormal and HLN models for dose from all nuclides and for radioiodine doses, respectively. These models, fitted to the sample distribution of exposures, permit extrapolation of the fitted curves out to 10 mrem/yr and beyond. These estimates derived from the fitted models are presented in Table 4-6, which contains estimates of the percentage and number of facilities exceeding 10 mrem/yr from all nuclides and exceeding 3 mrem/yr from radioiodine nuclides. In part A of the table, the lognormal and HLN estimates of the percentage and number of facilities with maximum individual dose exceeding 10 mrem/yr are quite different. The lognormal model estimates are 0.54 percent or approximately 33 facilities. Based on the analysis above, these estimates are high, since the lognormal model appears to overestimate the size of the upper tail. A more realistic estimate is given by the HLN model: 0.22 percent or 14 facilities may exceed 10 mrem/yr.

Radioiodine doses are analyzed in Part B of Table 4-6. The lognormal estimates are highlighted, since this model fits the upper tail of the sample distribution very poorly. The HLN model estimates that less than one facility will exceed 3 mrem/yr of radioiodine dose to the maximum individual.

Short of obtaining information and determining the doses to the public from every one of the roughly 6,000 facilities licensed by NRC or an Agreement State, some questions are likely always to remain. Although the HLN and lognormal models allow for the possibility that a relatively small number of facilities may exist that exceed the NESHAP limits, no facility studied was found to do so.

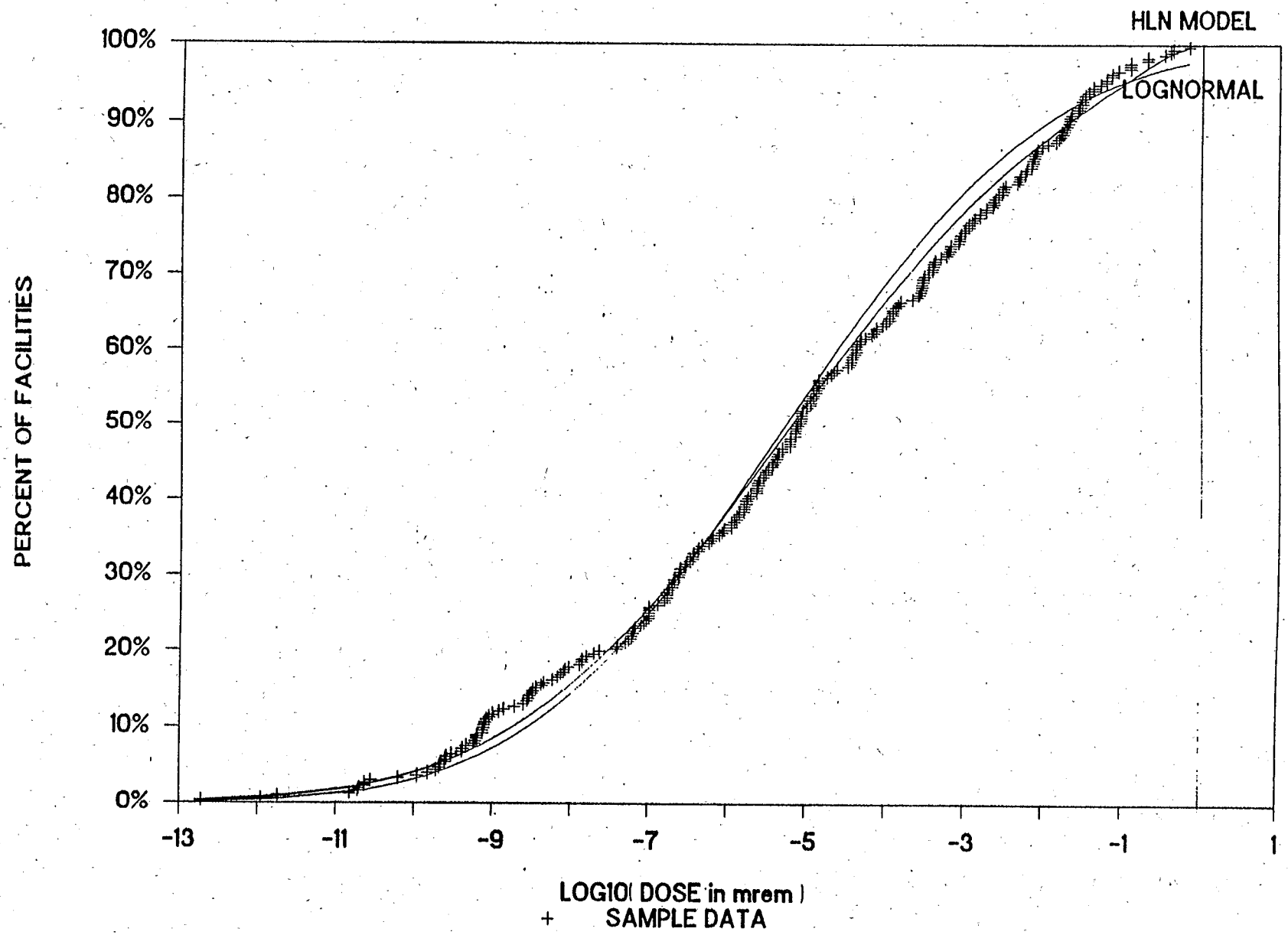

Figure 4-12. Cumulative Iodine Dose Distribution with Fitted Lognormal and HLN Models.

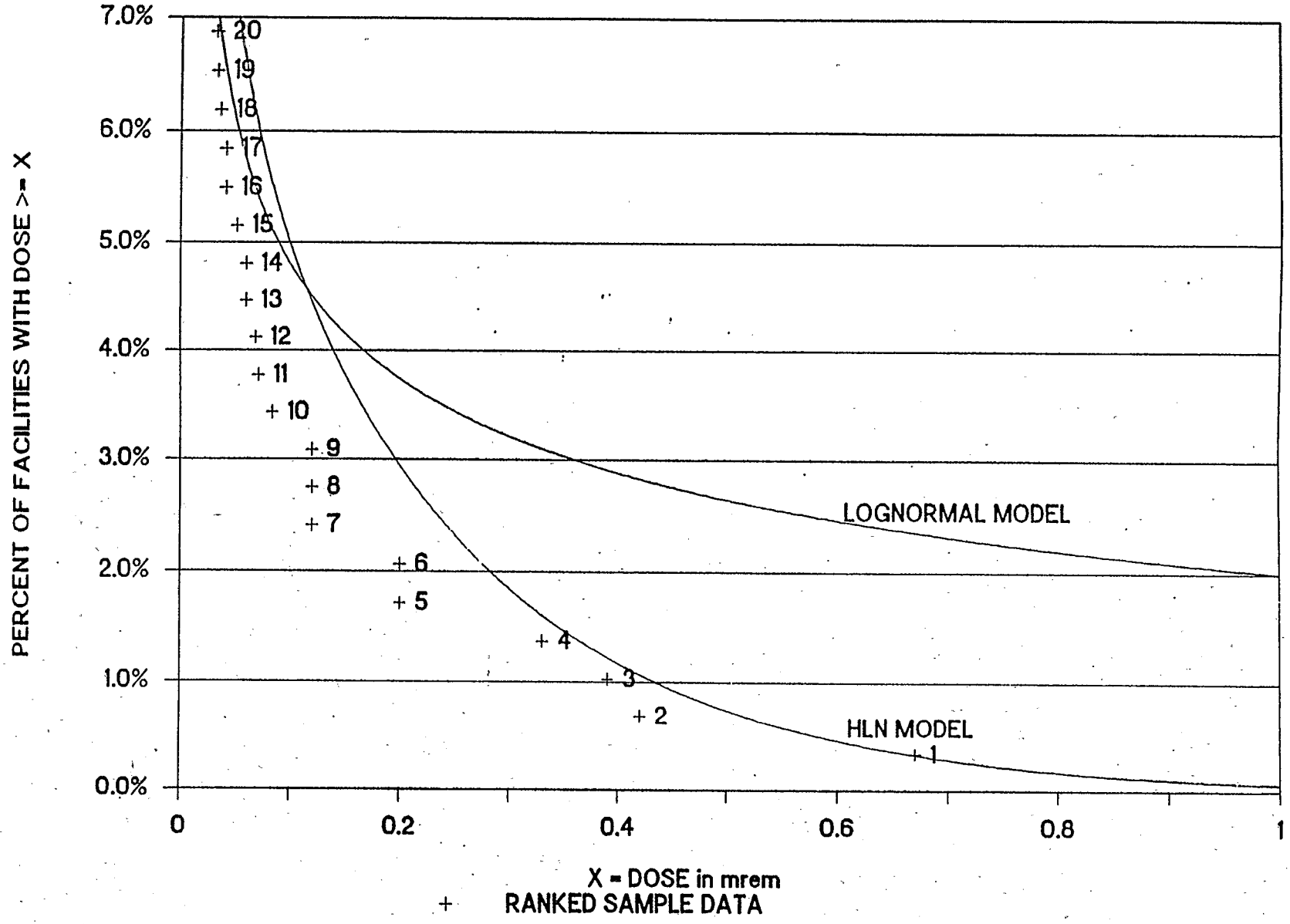

Figure 4-13. Extreme Tail of Iodine Distribution with Fitted Lognormal and HLN Models.

Table 4-6. Estimated percentage and number of facilities exceeding specified dose using the lognormal and hybrid-lognormal models.

A. Model-based estimates for dose from all nuclides			
Percent of Facilities Exceeding 10 mrem/yr		Number of Facilities Exceeding 10 mrem/yr (Out of 6,153 Facilities)	
Lognormal	HLN	Lognormal	HLN
0.54%	0.22%	33	14

B. Model-based estimates for dose from radioiodine			
Percent of Facilities Exceeding 3 mrem/yr		Number of Facilities Exceeding 3 mrem/yr (Out of 4,853 Facilities)	
Lognormal[1]	HLN	Lognormal[1]	HLN
1.26%	< 0.0000001%	61	< 1

1. Estimated values from the lognormal distribution are overstated due to over-estimation by the model of the upper tail of the sample radioiodine distribution.

5. Quality Control

Several planned and systematic actions were taken to provide confidence in the quality of the BID's results. These actions were designed to control activities affecting the quality of the dose calculations and the quality of the technical background information document.

First, EPA prepared a sample questionnaire to assess the licensees' ability to interpret EPA's needs and to respond with useful information. The samples were sent to a test group of NRC licensees and the responses analyzed. Based on these samples, EPA's questionnaires were modified to improve clarity for the formal mailings.

Second, all questionnaires received from licensees in response to the formal mailings were logged in to provide a traceable record. Technical analysts then reviewed the questionnaires to assure that the data submitted reflected a proper interpretation of the questionnaire's requirements. In several instances, the review suggested that licensees may have erred in filling out their forms. In all such cases, the respondents were contacted to discuss the items in question. Where appropriate, questionnaires were resubmitted with corrected data.

Third, a single analyst performed the initial set of calculations to assure a consistent approach in interpreting the respondents' questionnaires. To preclude the possibility that the single analyst was himself misinterpreting respondents' data, two independent analysts were asked to (a) verify the initial calculations by interpreting the data from the questionnaires and calculating the doses from the 50 facilities yielding the highest doses, and (b) review all assumptions made by the original analyst.

Finally, the entire manuscript was submitted for multi-disciplinary peer review.

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APPENDIX A

NRC's ORGANIZATION, REGULATIONS, AND CONTROLS

This appendix explains the origins and need for NRC and its predecessor, the Atomic Energy Commission, dating back to the Atomic Energy Act. It describes how NRC's organization promotes the discharge of its responsibilities and its ability to fulfill its legislative charter. Regulations and effluent controls for NRC-licensed facilities other than nuclear power reactors are described.

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APPENDIX A

NRC's ORGANIZATION, REGULATIONS, AND CONTROLS

A.1 ORGANIZATION AND RESPONSIBILITIES OF NRC

NRC regulates the civilian uses of source, byproduct, and special nuclear materials and nuclear reactors in the United States. This mission is accomplished through the development and implementation of controls (i.e., rules, regulations, guidance, etc.) governing licensed activities; licensing of nuclear facilities (i.e., issuance of permits and licenses) and the possession, use, and disposal of nuclear materials; and inspection and enforcement activities to ensure compliance with these controls and the conditions imposed through permits and licenses.

A.1.1 Basic Functions

NRC's responsibilities include protecting public health and safety; protecting the environment; protecting and safeguarding materials and plants in the interest of national security; and ensuring conformity with antitrust laws. During fiscal year 1990, NRC had approximately 3,200 employees and a budget of over $400 million to carry out three basic functions: regulatory research and standards development, licensing, and inspection and enforcement.

As part of its regulatory research and standards development function, NRC is mandated by law to conduct an extensive confirmatory research program in the areas of safety, safeguards, and environmental assessment. The Commission establishes regulations, standards, and guidelines governing the various licensed uses of nuclear facilities and materials.

In its licensing function, the agency reviews and issues licenses for the construction and operation of nuclear power plants and other nuclear facilities, and it licenses the possession and use of nuclear materials for medical, industrial, educational, research, and other purposes. Regulatory authority for certain nuclear materials licensing has been transferred to certain States under the Agreement States Program authorized by the AEA. However, NRC retains authority for licensing and regulating nuclear reactors.

NRC's inspection and enforcement activities include various kinds of inspections and investigations designed to ensure that licensed activities are conducted in compliance with its regulations and other requirements. NRC enforces compliance as necessary.

A.1.2 Organization

A.1.2.1 The Commission. The Commission is composed of five members, appointed by the President and confirmed by the Senate, one of whom the President designates as Chairman. The Chairman is the principal executive officer of, and the official spokesman for NRC, as mandated by the Reorganization Plan No. 1 of 1980 (NRC90). The Advisory Committee on Reactor Safeguards (ACRS), which was assigned a statutory role by Congress, independently reviews and reports on safety studies and applications for construction permits and operating licenses. The ACRS advises the Commission with regard to hazards at proposed or existing reactor facilities and the adequacy of proposed reactor safety studies. On its own initiative, the ACRS may review specific generic matters or nuclear facility safety issues.

A.1.2.2 NRC Offices. NRC reorganized in 1987 to reflect progressively less involvement with the construction of large, complex nuclear facilities and increased involvement with the operation and maintenance of these facilities.

Office of Nuclear Reactor Regulation (NRR). The primary responsibilities of this Office are to conduct the inspection and licensing activities associated with operating power reactors, including contractors and suppliers for such facilities. The Office also is responsible for evaluating applications to build and operate new power reactors, for inspection and licensing activities related to the construction and operation of research and test reactors, and for licensing reactor operators. In addition, the Office is responsible for inspecting NRC-licensed activities under its jurisdiction to ensure that they comply with all NRC regulations and requirements.

Except for research and test reactors, this Office has no responsibilities for NRC-licensed facilities other than nuclear power reactors.

Office of Nuclear Material Safety and Safeguards (NMSS). All non-reactor NRC licenses are regulated by the Office of Nuclear Material Safety and Safeguards (NMSS). NMSS's responsibilities fall into six principal areas: (1) licensing of nuclear fuel cycle

facilities, (2) licensing of nuclear materials for uses other than in reactors, (3) regulation of the transportation of nuclear materials, (4) safeguarding of nuclear materials from sabotage and diversion to unauthorized uses, (5) regulation of radioactive waste disposal facilities, and (6) regulation of the decommissioning of previously licensed nuclear facilities that are no longer in use. Some of these functions are carried out by the five NRC Regional Offices.

The various processing operations required to produce fuel for nuclear reactors are conducted in NRC-licensed fuel cycle facilities. Activities at these facilities include: certain types of uranium mining activities, milling and refining uranium ore to produce uranium concentrations, production of uranium hexafluoride from uranium concentrates to provide feed material for isotopic enrichment of U-235 to levels needed for a nuclear reaction, isotopic enrichment processing of uranium hexafluoride to produce fuel with a higher percentage of U-235 than in natural uranium, fabrication of nuclear reactor fuel, and reprocessing spent fuel for recycle.[1]

Most of the manufacturing operations that make up the nuclear fuel cycle are licensed by NRC. Exceptions are uranium mining, uranium milling in Agreement States, and enrichment by the U.S. Department of Energy. NMSS reviews operational safety, radiation protection, and criticality safety programs as part of the licensing process for fuel cycle facilities. NMSS also provides policy guidance and technical support to Agreement States on their licensing and inspection activities and on emergency responses. At present, NRC fuel cycle licenses number about 30.

NRC regulates approximately 8,200 licenses for the possession and use of radioactive materials for purposes other than the generation of electricity or operation of a research reactor. The 28 Agreement States regulate about 15,000 radioactive materials licenses. These totals include licensees authorized to possess and use radioactive materials only in the form of sealed sources. Most of NRC's licenses are administered by NRC's Regional Offices.

Office of Nuclear Regulatory Research (RES). This Office has three primary responsibilities: (1) to plan, recommend, and implement programs of nuclear regulatory research, standards development, and resolution of safety issues of facilities regulated by

[1] The latter step is not being performed in the United States.

NRC; (2) to develop and promulgate all technical regulations; and (3) to coordinate research activities within and outside the agency including appointment of staff to committees and conferences.

With respect to air emissions from NRC-licensed facilities other than nuclear power reactors, this Office is responsible for the promulgation and revision of regulations affecting emissions, such as 10 CFR Part 20. Additionally, the Office manages the development of regulatory guides.

Office for Analysis and Evaluation of Operational Data (AEOD). This Office independently analyzes and evaluates operational safety data associated with NRC-licensed activities to identify issues that require action by NRC or the industry. Its other responsibilities include the reactor performance indicators program and the management and direction of programs for diagnosing evaluations and investigations of significant operational events.

With respect to air emissions from NRC-licensed facilities other than nuclear power reactors, this Office evaluates semiannual plant airborne emissions data and unusual events that contribute to airborne emissions.

Office of Enforcement. This Office develops policies and programs for enforcement of NRC's requirements. It manages major enforcement actions and assesses the effectiveness and uniformity of enforcement actions taken by the Regional Offices. Enforcement powers include notices of violation, fines, and orders for license modification, suspension, or revocation.

Regional Offices. NRC's five Regional Offices execute the established NRC policies and assigned programs relating to inspection, enforcement, licensing, State agreements, State liaison, and emergency response within each region. Each regional division inspects and evaluates assigned NRC programs. For Part 70 licensees, NRC's Resident Inspector Program is applicable for assigned facilities. The Division of Radiation Safety and Safeguards performs inspections and evaluations in radiological safety and environmental monitoring.

A.1.2.3 State Programs. Prior to enactment of the Atomic Energy Act of 1954, nuclear energy activities in the United States were largely confined to the federal government. The Act made it possible for private commercial firms to enter the field for the first time. Because of the hazards associated with nuclear materials, Congress determined that these activities should be regulated under a federal licensing system to protect the health and safety of workers in the nuclear industry and the public. NRC is the federal agency charged with this responsibility.

Although protection of the public health and safety has traditionally been a State responsibility, the Atomic Energy Act of 1954 did not specify such a role for the States in nuclear matters. This policy was changed in 1959 when Congress enacted Section 274 of the Atomic Energy Act. Section 274 spells out a State role and provided a statutory basis under which the federal government can relinquish to the States portions of its regulatory authority. The 1959 amendment made it possible for the States to license and regulate byproduct material (radioisotopes), source material (the raw materials of atomic energy), and small quantities of special nuclear material.[2] The Commission is required, however, to retain regulatory authority over the regulation of nuclear facilities vital to the national common defense and security and certain types of radioactive wastes. The Atomic Energy Act was amended in 1978 by the passage of the Uranium Mill Tailings Radiation Control Act (UMTRCA) of 1978 which requires NRC Agreement States regulating uranium and thorium tailings or wastes resulting from recovery operations to adopt certain technical and procedural requirements. The 1978 amendment also requires NRC to review periodically Agreement State programs for adequacy and compatibility.

Section 274j of the Atomic Energy Act allows NRC to terminate its agreement with a State if the Commission finds that such termination is necessary to protect the public health and safety. In 1980, Section 274j was amended to authorize the Commission to suspend temporarily all or part of an agreement with a State in the case of an emergency situation where the State failed to take necessary action. Such suspensions may remain in effect only for the duration of the emergency.

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[2] In 1981, the Commission amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of low-level radioactive waste as a separate category.

The mechanism for the transfer of NRC authority to a State to regulate the radiological health and safety aspects of nuclear materials is a formal agreement between the Governor of the State and the Commission. Criteria for such agreements have been published by NRC as a Policy Statement in the *Federal Register*. Before actually signing the document, the Commission, by statute, must determine that the State's radiation control program is compatible with the Commission's, meets the applicable parts of Section 274, and is adequate to protect the public health and safety. For its part, the State establishes its authority to enter such an agreement by passing enabling legislation.

At present, 28 States have entered into such agreements with NRC.[3] These States now regulate over 65 percent of the 24,000 licensees for byproduct, source material, and special nuclear material in the United States. In 1981, the Commission determined that qualified States may also enter into limited agreements for regulation of low-level waste in permanent disposal facilities.

Each agreement provides that the State will use its best efforts to maintain continuing compatibility with the NRC's program. NRC maintains a continuing relationship with each Agreement State to assure continued compatibility of the State's regulatory program and its adequacy to protect health and safety. This relationship includes: exchange of current information covering regulations, licensing, inspection and enforcement data; consultation on special licensing, inspection, enforcement, and other regulatory problems; and an annual meeting of all Agreement States to consider regulatory matters of common interest. Special technical assistance is routinely provided to the States upon request.

As mandated by the Atomic Energy Act, NRC conducts onsite, in-depth program reviews periodically in each Agreement State. This review covers organizational, administrative, personnel, regulatory, licensing, compliance, and enforcement program areas. Selected Agreement State licensing and compliance casework is reviewed in detail. State inspectors are accompanied by NRC staff on selected inspections of State licensees. A copy of the guidelines that NRC uses in conducting such reviews have been published in the *Federal Register* as a Commission Policy Statement.

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[3] Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Washington.

NRC provides training for Agreement State personnel. Examples are short-term courses in health physics, radiography radiation safety, nuclear medicine, licensing, inspection procedures, radiological engineering, well-logging, transportation of nuclear materials, and project management for the licensing of low-level waste disposal facilities.

The NRC State Agreements Program is administered by the Office of State Programs. NRC Regional Offices participate in implementation of the State Agreements Program.

As a rule of thumb, one to one-and-a-half staff-years per 100 licenses is needed for effective administration of the program assumed from NRC. This is a general index, and actual staffing needs will vary according to the particular circumstances in any given State.

The Agreement State experience since 1962, the year of the first State agreement, has been that the States generally conduct effective radiation control programs. When NRC notes major program deficiencies, NRC (with its resources) offers technical advice, assistance, and training. The main area of concern is maintaining adequate staffing levels, a reflection of State salary structures and funding. On the other hand, Agreement States typically excel in having highly trained staff and in conducting more frequent inspections than NRC.

A.2 CONTROLS APPLICABLE TO LICENSEES - GENERAL

A.2.1 Establishing Airborne Emission Controls

This section describes NRC's procedures for setting facility controls to protect the health and safety of the public. These controls may take several forms: rules and regulations; regulatory guides; generic letters, bulletins, and information notices; and NRC reports. The first two categories of controls for facilities are administered by the Office of Nuclear Regulatory Research (RES); the others are administered by the Office of Nuclear Reactor Regulation (NRR).

A.2.1.1 Rulemaking and Regulatory Guides. The term rulemaking actually covers the establishment of two kinds of regulatory documents - the regulations of NRC contained in Title 10 of the *Code of Federal Regulations* (10 CFR) and regulatory guides. The decision to move forward with either a rule or a regulatory guide is based upon the results of a

regulatory analysis (itself based upon a Technical Findings Document [e.g., NUREG]). Thereafter, both types of documents, rules and guides, are developed in a process that provides for internal and external (public) review and comment. The entire process is repeated again for the final rule or guide, developed in light of comments received from the public.

Both types of documents are prepared in a two-step process. In the first step, a draft is produced for public comment. RES usually develops such drafts in consultation with and on behalf of NRR, NMSS, or both. The drafts are developed at a technical staff level, coordinated through parallel management chains of the affected offices, reviewed by the appropriate advisory committee (usually the ACRS except for waste management matters which now have their own advisory committee), reviewed by a senior management review group called the Committee for the Review of Generic Requirements (CRGR), and then presented to the appropriate decision maker(s) for action.

When the development of a rule or a guide reaches the point where it is presented to the decision makers, the process diverges. Substantive rules can be issued for public comment only by a majority vote of the five NRC Commissioners. Therefore, proposed rulemakings are recommended for action by RES, with the concurrence of the affected program office, through the NRC's Executive Director for Operations, to the Commission. The Commission requests input from the appropriate advisory committees and the CRGR to assist in its decision.

Once the Commission has decided to issue a proposed rule for public comment, a notice of the proposed action is issued in the *Federal Register*; the notice also identifies the time allowed for comments and may specify particular questions on which the Commission desires input. These particular questions often involve the matters treated in the regulatory analysis performed for the proposed rule; e.g., the anticipated costs and other impacts of imposing the new rule.

The RES staff, in consultation with the affected program office, evaluates public comments received on a proposed rule. The Commission has used both rulemaking hearings, which are formal adjudicatory proceedings, and public meetings, which are less formal, to further discussion and obtain additional information concerning a proposed rule. Once the additional information has been received and evaluated, the staff modifies the rule as

necessary, repeats the entire review process followed for the proposed rule, and returns the rulemaking package to the Commission for final action. When the Commission makes its final decision on the rule, it is issued as "effective" with a notice in the *Federal Register*. The rule then becomes a part of Title 10 of the *Code of Federal Regulations*.

The process followed by the RES in developing a draft and then a final regulatory guide is essentially the same as that for a rule, except that the Executive Director for Operations and the Commission are not involved. Rather, the Director of the Office of RES is the final decision authority for issuing regulatory guides, either in draft form for public comment or in final form.

A.2.1.2 Generic Letters, Bulletins and Information Notices. Generic letters, bulletins, and information notices are written NRC notifications sent to groups of licensees that identify specific problems, developments, or other matters of interest to the licensees. In some cases, NRC is calling for or recommending that the licensees take specific steps.

A.2.1.3 NRC Reports. NRC reports (usually referred to generically as NUREGs) are prepared by NRC's staff, contractors, or national laboratories and provide the technical basis for decision making. Special categories of such reports include Safety Evaluation Reports (SERs), Environmental Impact Statements (EISs), and Standard Review Plans (SRPs). NRC issues the first two categories of reports to establish the conditions under which the license to construct or operate will be issued. The SRPs are issued to disseminate information about the regulatory licensing process and to improve the general public's and the nuclear industry's understanding of the staff's review process.

Standard Review Plans address the responsibilities of the persons performing the review, the matters that are reviewed, the Commission's regulations and acceptance criteria necessary for the review, how the review is accomplished, the appropriate conclusions, and the implementation requirements.

A.2.2 Licensing Program

Licensing programs utilize a system of controls, compliance guidance, and independent review to establish (with reasonable assurance) the ability of a facility to meet performance requirements. Of particular relevance is NRC's ability to establish and maintain

an acceptable level of performance through (1) independent review to verify that regulatory criteria were correctly translated into design, construction, and operations documents and (2) monitoring of operating data.

NRC has delegated to the five Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials. The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR Parts 30 through 35, 39, 40, and 70 to all persons for academic, medical, and industrial uses, with the exceptions of activities in the fuel cycle and special nuclear material, sealed sources and devices design review, and processing of source material for extracting of metallic compounds.

A.2.2.1. Part 30 Licenses. The regulations in 10 CFR Parts 30, 32, 33, 35, and 39 provide for licensing facility categories listed in Table D-1. A license applicant is required to file an application in duplicate on NRC Form 313, "Application for Material License," in accordance with the instructions in 10 CFR 30.6 and 30.32. Form 313 asks a wide range of information including: the name and mailing address of the applicant; the location of use; a person who can be contacted about the application; the materials requested; the purpose of use; the training and experience of the authorized users and Radiation Safety Officer; the worker radiation safety training program; facilities and equipment; the radiation safety program; and waste management program. The information will be transformed into license conditions upon approval. The applicant mails the license application, with application fee, to the NRC office identified on the form.

Because of the potential radiation hazard to workers and the public, NRC's specific license program for regulating byproduct material use incorporates three regulatory features: case-by-case review of applications, onsite inspections, and periodic license renewals. NRC staff will review the application to determine whether the applicant's radiation safety program complies with the regulations. After completing the review, if the applicant's program appears incomplete or inadequate, NRC will issue a deficiency letter that describes the apparent shortcomings in the applicant's program and requests clarification or correction. If the applicant's response to the deficiency letter is satisfactory, or if no deficiency letter was needed, NRC will issue a specific license authorizing the possession and use of byproduct material on NRC Form 374, "Byproduct Material License."

To help license applicants prepare the application and design their radiation safety programs, NRC has published the following guidance documents:

• Regulatory Guide 8.18	Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable
• Regulatory Guide 8.21	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
• Regulatory Guide 8.23	Radiation Safety Surveys at Medical Institutions
• Regulatory Guide 10.2	Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope
• Regulatory Guide 10.5	Applications for Type A Licenses of Broad Scope
• Regulatory Guide 10.7	Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material
• Regulatory Guide 10.8	Guide for the Preparation of Applications for Medical Programs
• Draft Guide DG-8001	Basic Quality Assurance Program for Medical Use
• Draft Guide OP 212-4	Radiation Protection Training for Personnel Employed in Medical Facilities
• NUREG-0267	Principles and Practices for Keeping Occupational Radiation Exposure at Medical Institutions As Low As Reasonably Achievable

A.2.2.2. Part 40 Licenses. The regulations in 10 CFR Part 40, "Domestic Licensing of Source Material," provide for licensing facility categories listed in Table D-1. A license applicant is required to provide detailed information on the facilities, equipment, and procedures to be used and an environmental report discussing the operation's impact on the health and safety of the public and on the environment. The Commission uses this information to determine whether the applicant's proposed activities will, among other things, result in undue risk to the health and safety of the public or adversely affect the environment. General guidance for filing an application and an environmental report is provided in Section

40.31, "Application for Specific Licenses," of 10 CFR Part 40, and in 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," respectively.

The application must contain information specified in NRC Form 313, "Application for Material License," which primarily addresses processing, in-plant radiation safety, and environmental considerations. In essence, the applicant is required to submit, as part of the license application, a Safety Analysis Report (SAR) pursuant to 40 CFR Part 190 and an Environmental Report (ER) pursuant to 10 CFR Part 51. Based on the information provided in these reports, NRC will in turn develop a Safety Evaluation Report (SER) and an Environmental Impact Statement (EIS). Under 10 CFR 51.22, "Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or Otherwise Not Requiring Environmental Review," some licensees are not required to prepare an Environmental Report if NRC's first finding is that the applicant's proposed actions do not individually or cumulatively have a significant effect on the human environment.

These licenses are generally issued for 10-year periods and are renewable over the life of the project. License renewal applications are processed in a manner similar to that used for new applications. Operational experience, site-specific data, and proposed continuing activities are the primary factors considered by the NRC staff in processing renewal applications.

To help licensees develop the application, NRC has published the following guidance documents (a comprehensive list is provided in Appendix B):

- Regulatory Guide 3.5 — Standard Format and Content of License Applications for Uranium Mills
- Regulatory Guide 3.8 — Preparation of Environmental Reports for Uranium Mills
- Regulatory Guide 3.46 — Standard Format and Content of License Applications, Including Environmental Reports, for In Situ Uranium Solution Mining
- Regulatory Guide 3.51 — Calculational Models for Estimating Radiation Doses to Man from Airborne Radioactive Materials Resulting from Uranium Milling Operations

•	Regulatory Guide 3.55	Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Hexafluoride Production
•	Regulatory Guide 3.56	General Guidance for Designing, Testing, Operating, and Maintaining Emission Control Devices at Uranium Mills
•	Regulatory Guide 3.59	Methods for Estimating Radioactive and Toxic Airborne Source Terms for Uranium Milling Operations
•	Regulatory Guide 4.4	Radiological Effluent and Environmental Monitoring at Uranium Mills
•	Regulatory Guide 4.15	Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment
•	Regulatory Guide 8.30	Health Physics Surveys in Uranium Mills
•	Regulatory Guide 8.31	Information Relevant to Ensuring that Occupational Radiation Exposures at Uranium Mills Will Be As Low As Is Reasonably Achievable
•	NUREG/CR-2011	MILDOS - A Computer Program for Calculating Environmental Radiation Doses from Uranium Recovery Operations

A.2.2.3. Part 50 (Type 104) Licenses. The licensing process begins with the filing of a license application, consisting of general information, an Environmental Report, and a Safety Analysis Report (SAR). The general content requirements of the SAR for a reactor are contained in 10 CFR 50.34.

NRC initiates a comprehensive technical review of the license application and any supporting documents after initial acceptance review and docketing. During this period, NRC's staff and the Advisory Committee on Reactor Safeguards (ACRS) conduct independent technical reviews of the license application, resulting in the issuance of a Safety Evaluation Report (SER) by NRC's staff and a formal letter of recommendation from the ACRS to the Chairman of NRC.

In determining whether to grant a construction permit, NRC holds an adjudicatory public proceeding conducted by the Atomic Safety and Licensing Board (ASLB). At the end of the adjudicatory proceeding, the ASLB renders a decision supported by a written opinion. A decision of the ASLB could be appealed to an Atomic Safety and Licensing Appeal Board (ASLAB). The Commissioners may also consider the matter upon a petition requesting such review. After all avenues of administrative appeal have been exhausted and if the ASLB's initial decision prevails, the Director of Nuclear Reactor Regulation issues a letter authorizing construction to begin.

Prior to anticipated completion of construction, the applicant submits an updated license application to NRC in support of obtaining a license to operate. NRC's staff and the ACRS again conduct technical reviews which, if favorable, result in the issuance of a Safety Evaluation Report by NRC's staff and a formal letter of recommendation from the ACRS to the Chairman of NRC.

A.2.2.4. Part 70 Licenses. The regulations in 10 CFR Part 70, "Domestic Licensing of Source Material," provide for licensing facility categories listed in Table D-1. A license applicant is required to provide detailed information on the facilities, equipment, and procedures to be used and an environmental report that discusses the operation's impact on the health and safety of the public and on the environment. The Commission uses this information to determine whether the applicant's proposed activities will, among other things, result in undue risk to the health and safety of the public or adversely affect the environment. The license application can be filed in letter form and provides the information specified in section 70.22, "Contents of Applications."

General guidance for filing an application and an environmental report is provided in Section 70.21, "Filing," of 10 CFR Part 70 and in 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," respectively. Basically, the applicant is required to submit, as part of the license application, a Safety Analysis Report (SAR) pursuant to 40 CFR Part 190 and an Environmental Report (ER) pursuant to 10 CFR Part 51. Based on the information provided in these reports, NRC will in turn develop a Safety Evaluation Report (SER) and an Environmental Impact Statement (EIS). Under 10 CFR 51.22, "Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or Otherwise Not Requiring Environmental Review," some licensees are not required to prepare an Environmental Report

if NRC first finds that the applicant's proposed actions do not individually or cumulatively have a significant effect on the human environment.

These licenses are generally issued for 10-year periods and are renewable over the life of the project. License renewal applications are processed in a manner similar to that used for new applications. Operational experience, site-specific data, and proposed continuing activities are the primary factors considered by the NRC staff in processing renewal applications.

To help licensees prepare the application, NRC has published the following guidance documents (a comprehensive list is provided in Appendix B):

- Regulatory Guide 3.6 — Content of Technical Specifications for Fuel Reprocessing Plants
- Regulatory Guide 3.12 — General Design Guide for Ventilation Systems of Plutonium Processing and Fuel Fabrication Plants
- Regulatory Guide 3.25 — Standard Format and Content of Safety Analysis Reports for Uranium Enrichment Facilities
- Regulatory Guide 4.9 — Preparation of Environmental Reports for Commercial Uranium Enrichment Facilities
- Regulatory Guide 8.10 — Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable
- Regulatory Guide 10.3 — Guide for the Preparation of Applications for Special Nuclear Material Licenses of Less Than Critical Mass Quantities

A.2.3 Airborne Emissions Monitoring

During the period of operation, the licensee is subject to various terms and conditions to ensure that activities are conducted in accordance with the design bases and performance objectives agreed to in the license. Airborne effluent monitoring programs and inspections are means by which NRC monitors facility operations.

NRC regulations limiting routine radionuclide airborne emissions are contained in 10 CFR Part 20, Standards for Protection Against Radiation, which applies to all licensees. In addition, the recent amendments to Part 20 require licensees by January 1994 to keep exposures as low as is reasonably achievable (ALARA). ALARA means making every reasonable effort to maintain exposures to radiation as far below the dose limits in 10 CFR Part 20 as is practical, consistent with the purpose for which the licensed activity is undertaken. The requirement takes into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and the value of utilizing nuclear energy and licensed materials in the public interest.

A.2.3.1 Part 30 Licenses. The possible airborne radionuclide emissions are from unsealed byproduct material on foils or plated sources or radioactive aerosols or gases in a manufacturing facility, laboratory, or radiopharmaceutical. In general, facility design or engineered safety features in the facility and operating restrictions or procedures would reduce airborne radionuclide release. Use of charcoal traps or fume hoods with charcoal filtration system or HEPA filter can significantly reduce air contamination during operations.

Incineration operations (e.g., at hospitals) must be conducted in a way that all airborne effluent releases are reduced to levels as low as reasonably achievable (ALARA). The primary means of accomplishing this objective is emission controls including filtration, scrubbing, and air dilution. Discharge stacks, types and estimated composition and flow rates of atmospheric effluents, and emissions control methods must be designed and analyzed to limit potential releases to ALARA levels.

For medical use of byproduct materials, according to 10 CFR 35.205:

(a) A licensee that administers radioactive aerosols or gases is required to do so in a room with a system that will keep airborne concentrations within the limits prescribed by 10 CFR 20.106. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(b) A licensee is required to administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

(c) Before receiving, using, or storing a radioactive gas, the licensee is required to calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limits listed in Appendix B to 10 CFR Part 20. The calculation must be based on the highest activity of a gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(d) A licensee is required to make a record of the calculations required in (c) that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee is also required to post the calculated time and safety measures to be instituted in case of a spill at the areas of use.

(e) A licensee is required to check the operation of reusable collection systems each month and measure the ventilation rate available in areas of radioactive gas use each 6 months. In addition, according to 10 CFR 35.90, a licensee is required to store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee is also required to store a multi-dose container in a fume hood after drawing the first dosage from it.

Airborne effluent concentration at the release point must be calculated and compared to the appropriate value of Table II of Appendix B to 10 CFR Part 20. NRC or the Agreement State often recommends that the license applicant use a "10 percent at the stack" rule for the calculation. Except for medical institutions, this calculation is required to be submitted as part of the license application under Item 10.13.3 of Form NRC-313. Medical license applicants do not have to submit the calculations with the application, but they are required to keep them on record for NRC (or Agreement State) review during onsite inspections.

If aerosols and gases are not directly vented to the atmosphere, the license applicant may respond with a statement that it will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary. If aerosols or gases are directly vented to the atmosphere, airborne effluent concentrations must be calculated. For medical institutions, NRC recommends the following estimation procedure, described in Regulatory Guide 10.8, for use in the license application:

(a) Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on time" multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.

(b) If this is not the case, plan for fewer studies and do the calculation again. Alternatively, consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

A.2.3.2 Part 40 Licenses. To achieve airborne emission control, facility operations must be conducted in a way that reduces all airborne effluent releases to levels that are ALARA. The primary means of accomplishing this objective is by means of emission controls including ventilation, filtration, and confinement systems. Discharge stacks, types and estimated composition and flow rates of atmospheric effluents, and emission control methods are required to be designed and analyzed to limit potential releases to ALARA levels. Calculations must be supplemented by stack monitoring appropriate for the planned and potential releases. Minimum performance specifications, such as filtration or scrubber efficiency and airflow for operating the ventilation, filtration, and confinement systems throughout the facility, are normally determined.

Institutional controls, such as extending the site boundary and exclusion area, are also employed to ensure that offsite exposure limits are met, but only after all practical measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are reduced to the maximum extent reasonably achievable and to avoid site contamination.

Effluent and environmental monitoring programs, including methods and procedures for measuring concentrations and quantities of both radioactive and nonradioactive materials released to and in the environs, must comply with the technical basis specified in Sections 20.1301 and 20.1302 of 10 CFR Part 20. For both effluent and environmental monitoring, the frequency of sampling and analysis, the types and sensitivity of analysis, action levels and corrective action requirements, and the minimum number and criteria for locating effluent and environmental monitoring stations also must be determined. A survey program is essential to monitor the adequacy of containment and effluent control.

From release rates of airborne radioactivity, meteorological data, and locations of release points (e.g. stack, roof vent), total annual body and significant organ doses can be estimated for (1) individuals exposed at the point of maximum ground-level concentrations off site, (2) individuals exposed at the site boundary in the direction of the prevailing wind,

(3) individuals exposed at the site boundary nearest to the sources of emission, and (4) individuals exposed at the nearest residence in the direction of the prevailing wind. The license applicant must also estimate deposition of radioactive materials on food crops and pasture grass, and total annual body doses and significant annual doses received by other organs via such potential pathways to the public. The licensee is required to demonstrate compliance with the exposure limits specified in 10 CFR Part 20 and 40 CFR Part 190 and also effluent concentrations set forth in Table 2 of Appendix B of 10 CFR Part 20.

Each licensee is required to submit a semiannual effluent monitoring report to the appropriate NRC Regional Office, specifying the quantity of each of the principal radionuclides released to unrestricted areas in gaseous (and in liquid) effluents during the previous 6 months of operations. The licensee must also submit such other information that NRC may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases. If quantities of radioactive materials released during the reporting period are significantly above the licensee's design objectives previously reviewed as part of the licensing action, the report shall cover this specifically.

A.2.3.3 Part 50 (Type 104) Licenses: Changes, Tests, and Experiments (10 CFR 50.59). Once a license to operate has been issued, NRC allows changes in facility design, operational procedures, and activities unless the proposed change involves a modification to the technical specifications or an unreviewed safety question. The licensee is required to maintain records and to report all changes in facility descriptions or procedures contained in the FSAR.

Records and Reports (10 CFR 50.71). Each licensee and each holder of a construction permit is required to maintain records and make reports in accordance with the conditions established in the license or permit, or by the rules, regulations, and orders of the Commission.

Backfitting (10 CFR 50.109). The Commission may require backfitting of a facility if it finds that such action is necessary to protect public health and safety or that it will provide substantial, additional protection at a justifiable cost.

A.2.3.4 Part 70 Licenses. The requirements for airborne emissions monitoring are essentially the same as for Part 40 licensees.

A.2.4 Inspection Programs

The fuel cycle facility inspection program is described in Chapter 2600 (NRC90a). The materials licenses inspection program is described in detail in NRC Manual Chapter 2800 (NRC90b).

Initial inspections of licensees are generally conducted within 6 months to 1 year after material is received and operations under the license have begun.

In conjunction with the licensee's required semiannual effluent monitoring reports to NRC, the inspections determine the degree to which each plant is complying with its license and technical specifications. If problems are identified, follow-up inspections are scheduled in order to ensure that deficiencies are corrected. If a facility has persistent problems in particular areas, inspections are performed more frequently.

A.2.4.1 Part 30 Licenses. The inspection frequency for the various procedures at these facilities is:

- Medical Institution Broad & Medical Institution Other -various, every 1 to 5 years, average 18 months
- Medical Private Practice - various, 1 to 5 years
- Well-Logging - every 3 years
- Manufacturing and Distribution Licenses - various, every 1 to 5 years
- Incineration Licenses - yearly

A.2.4.2 Part 40 Licenses. Initial inspection of licenses are generally conducted within 6 months to 1 year after material is received and operations under the license have begun. The frequency of subsequent inspections is shown below:

- Mills - at least once every year
- Military Munitions Testing - every 3 years
- Uranium Hexafluoride Production - at least once every year
- Rare Earth Extraction and Processing - every 3 years

A.2.4.3 Part 50 (Type 104) Licenses. Inspections (10 CFR 50.70). Each licensee (and holder of a construction permit) must permit NRC to inspect its records, premises, and activities. The licensee is required to provide office space onsite for a full-time NRC resident inspector.

A.2.4.4 Part 70 Licenses. The inspection program described in Section A.2.4.2 for Part 40 licenses applies, except for the following frequencies:

- Uranium Fuel Fabrication - at least once every year
- Interim Spent Fuel Storage - at least once every year

A.2.5 Enforcement Programs

The objective of the NRC's enforcement programs is to protect the public health and safety by ensuring that licensees comply with regulatory requirements. The NRC's enforcement policy, contained in 10 CFR Part 2, Appendix C, calls for strong enforcement measures to ensure full compliance and is designed to prohibit operations by any licensees who fail to achieve adequate levels of protection.

NRC's enforcement action has several levels of severity. The level of severity used in a given situation varies with the seriousness of the matter and the licensee's previous compliance record. The levels include:

- Written Notices of Violation -- used in all instances of noncompliance with NRC's requirements.

- Civil penalties -- considered for licensees who evidence significant or repetitive instances of noncompliance, especially if a previous Notice of Violation has not been effective in achieving the expected corrective action. Civil penalties may also be imposed in the case of a particularly significant first-of-a-kind violation.

- Orders to "cease and desist" operations, or for modification, suspension, or revocation of licenses -- used in situations where licensees have not responded to civil penalties or where violations pose a significant threat to public health and safety or the common defense and security.

A.3 CONTROLS APPLICABLE TO AIRBORNE EMISSIONS

Current regulations limiting routine radionuclide airborne emissions from NRC-licensed facilities are forth in 10 CFR 20 and 40 CFR 190. Part 20 establishes "Standards for Protection Against Radiation." The recent revisions to Part 20 establish a new limit of 100 mrem/yr for members of the public. The 100 mrem/yr limit covers doses from both

gaseous and liquid effluents and considers exposures from all sources. Part 20 also imposes the requirement that exposures be as low as reasonably achievable (ALARA). Licensees may demonstrate compliance with this limit using the effluent concentrations set forth in Table 2 of Appendix B of 10 CFR Part 20. The values in Table 2 for air are based on 50 mrem/yr.

EPA's environmental radiation standards for fuel cycle facilities are set forth in 40 CFR Part 190. 40 CFR 190 requires, in part, that the radiation doses to real individuals from all uranium fuel cycle sources, including all gaseous and liquid effluent pathways and direct radiation, should not exceed 25 mrem/yr to the whole body or any organ, except the thyroid. The dose limit to the thyroid is established at 75 mrem/yr.

A.4 REFERENCES

NRC90 U.S. Nuclear Regulatory Commission, "U.S. Nuclear Regulatory Commission Functional Organizational Charts," NUREG-0325, Revision 14, August 1990.

NRC90a U.S. Nuclear Regulatory Commission, "NRC Inspection Manual, Chapter 2600, Fuel Cycle Facility Operational Safety Inspection Program," March 1990.

NRC90b U.S. Nuclear Regulatory Commission, "NRC Inspection Manual, Chapter 2800, Materials Inspection Program," April 1990.

APPENDIX B

SELECTED NRC REGULATORY GUIDES

This appendix provides a partial list of the regulatory guides published by NRC that are relevant to airborne effluents from nonreactor NRC-licensed facilities.

NO.	TITLE	REV.	DATE
	DIVISION 2 - RESEARCH AND TEST REACTORS		
2.2	Development of Technical Specifications for Experiments in Research Reactors	-	11/73
	DIVISION 3 - FUELS AND MATERIALS FACILITIES		
3.2	Efficiency Testing of Air-Cleaning Systems Containing Devices for Removal of Particles	-	01/73
3.3	Quality Assurance Program Requirements for Fuel Reprocessing Plants and for Plutonium Processing and Fuel Fabrication Plants	- 1	01/73 03/74
3.5	Standard Format and Content of License Applications for Uranium Mills	- 1	02/73 11/77
3.6	Content of Technical Specifications for Fuel Reprocessing Plants	-	04/73
3.7	Monitoring of Combustible Gases and Vapors in Plutonium Processing and Fuel Fabrication Plants	-	03/73
3.8	Preparation of Environmental Reports for Uranium Mills	- 1 2	04/73 09/78 10/82
3.12	General Design Guide for Ventilation Systems of Plutonium Processing and Fuel Fabrication Plants	-	08/73
3.25	Standard Format and Content of Safety Analysis Reports for Uranium Enrichment Plants	-	12/74
3.26	Standard Format and Content of Safety Analysis Reports for Fuel Reprocessing Plants	-	02/75
3.32	General Design Guide for Ventilation Systems for Fuel Reprocessing Plants	-	04/77
3.33	Assumptions Used for Evaluating the Potential Radiological Consequences of Accidental Nuclear Criticality in a Fuel Reprocessing Plants	-	09/75
3.34	Assumptions Used for Evaluating the Potential Radiological Consequences of Accidental Nuclear Criticality in a Uranium Fuel Fabrication Plant	- 1	04/77 07/79
3.35	Assumptions Used for Evaluating the Potential Radiological Consequences of Accidental Nuclear Criticality in a Plutonium Processing and Fuel Fabrication Plants	- 1	05/77 07/79
3.39	Standard Format and Content of License Applications for Plutonium Processing and Fuel Fabrication Plants	-	01/76
3.42	Emergency Planning for Fuel Cycle Facilities and Plants Licensed Under 10 CFR Parts 50 and 70	- 1	08/77 09/79
3.44	Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation (Water-Basin Type)	- 1 2	12/78 11/80 01/89
3.46	Standard Format and Content of License Applications, Including Environmental Reports, for In Situ Uranium Solution Mining	-	06/82
3.48	Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation or Monitored Retrievable Storage Installation (Dry Storage)	1	08/89
3.49	Design of an Independent Spent Fuel Storage Installations (Water-Basin Type)	-	12/81
3.51	Calculational Models for Estimating Radiation Doses to Man from Airborne Radioactive Materials Resulting from Uranium Milling Operations	-	03/82
3.52	Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Processing and Fuel Fabrication	- 1	07/82 11/86
3.55	Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Hexaflouride Production	-	04/85
3.56	General Guidance for Designing, Testing, and Maintaining Emission Control Devices at Uranium Mills	-	05/86

3.59	Methods for Estimating Radioactive and Toxic Airborne Source Terms for Uranium Milling Operations	-	03/87
3.60	Design of an Independent Spent Fuel Storage Installation (Dry Storage)	-	03/87
3.61	Standard Format and Content for a Topical Safety Analysis Report for a Spent Fuel Dry Storage Cask	-	02/89
3.62	Standard Format and Content for the Safety Analysis Report for Onsite Storage of Spent Fuel Storage Casks	-	02/89
3.63	Onsite Meteorological Measurement Program for Uranium Recovery Facilities - Data Acquisition and Reporting	-	03/88
3.64	Calculation of Radon Flux Attenuation by Earthen Uranium Mill Tailings Covers	-	06/89
3.65	Standard Format and Content of Decommissioning Plans for Licenses Under 10 CFR Parts 30, 40, and 70	-	08/89
	DIVISION 4 - ENVIRONMENTAL AND SITING		
4.1	Programs for Monitoring Radioactivity in the Environs of Nuclear Power Plants	- 1	01/73 04/75
4.5	Measurements of Radionuclides in the Environment - Sampling and Analysis of Plutonium in Soil	-	05/74
4.6	Measurements of Radionuclides in the Environment - Strontium-89 and Strontium-90 Analyses	-	05/74
4.9	Preparation of Environmental Reports for Commercial Uranium Enrichment Facilities	- 1	12/74 10/75
4.13	Performance, Testing, and Procedural Specifications for Thermoluminescence Dosimetry: Environmental Applications	- 1	11/76 07/77
4.14	Radiological Effluent and Monitoring at Uranium Mills	- 1	06/77 04/80
4.15	Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment	- 1	12/77 02/79
4.16	Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Reprocessing and Fabrication Plants and Uranium Hexaflouride Production Plants	- 1	03/78 12/85
4.17	Standard Format and Content Guide of Site Characterization Plans for High-Level-Waste Geologic Repositories	- 1	07/82 03/87
4.18	Standard Format and Content of Environmental Reports for Near-Surface Disposal of Radioactive Waste	-	06/83
	DIVISION 5 - MATERIALS AND PLANT PROTECTION		
5.4	Standard Analytical Methods for the Measurement of Uranium Tetraflouride (UF_4) and Uranium Hexaflouride (UF_6)	-	02/73
5.5	Standard Methods for Chemical, Mass Spectrometric, and Spectrochemical Analysis of Nuclear-Grade Uranium Dioxide Powders and Pellets	-	02/73
5.13	Conduct of Nuclear Material Physical Inventories	-	11/73
5.18	Limit of Error Concepts and Principles of Calculation in Nuclear Materials Control	-	01/74
5.24	Analysis and Use of Process Data for the Protection of Special Nuclear Material	-	06/74
5.33	Statistical Evaluation of Material Unaccounted For	-	06/74
5.42	Design Considerations for Minimizing Residual Holdup of Special Nuclear Material in Equipment for Dry Process Operations	-	01/75
5.45	Standard Format and Content for the Special Nuclear Material Control and Accounting Section of a Special Nuclear Material License Application (Including That for a Uranium Enrichment Facility)	-	12/74

5.51	Management Review of Nuclear Material Control and Accounting Systems	- 	06/75
5.58	Considerations for Establishing Traceability of Special Nuclear Material Accounting Measurements	- 1	11/78 02/80
5.62	Reporting of Safeguards Events	- 1	02/81 11/87
	DIVISION 8 - OCCUPATIONAL HEALTH		
8.2	Guide for Administrative Practices in Radiation Monitoring	-	02/73
8.10	Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable	- 1 1-R	04/74 09/75 05/77
8.18	Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable	- 1	12/77 10/82
8.21	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants	- 1	05/78 10/79
8.23	Radiation Safety Surveys at Medical Institutions	- 1	02/79 01/81
8.24	Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication	- 1	11/78 10/79
8.25	Calibration and Error Limits of Air Sampling Instruments for Total Volume of Air Sampled	-	08/80
8.30	Health Physics Surveys in Uranium Mills	-	06/83
8.31	Information Relevant to Ensuring that Occupational Radiation Exposures at Uranium Mills Will Be As Low As Reasonably Achievable	-	05/83
	DIVISION 10 - GENERAL		
10.1	Compilation of Reporting Requirements for Persons Subject to NRC Regulations	- 1 2 3 4	01/75 07/75 08/75 05/77 10/81
10.2	Guidance to Academic Institutions Applying for Special Nuclear Material Licenses of Limited Scope	- 1	03/76 12/76
10.3	Guide for the Preparation of Applications for Special Nuclear Material Licenses of Less Than Critical Mass Quantities	- 1	07/76 04/77
10.4	Guide for the Preparation of Applications for Licensees to Process Source Material	- 1 2	07/76 03/77 12/87
10.5	Applications for Type A Licenses of Broad Scope	- 1	09/76 12/80
10.7	Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material	- 1	02/77 08/79
10.8	Guide for the Preparation of Applications for Medical Use Programs	- 1 2	01/79 10/80 08/87
10.10	Guide for the Preparation of Applications for Radiation Safety Evaluations and Registration of Devices Containing Byproduct Material	-	03/87

APPENDIX C

DESCRIPTION OF NRC AND AGREEMENT STATE LICENSED ACTIVITIES

This appendix describes the activities for which an NRC or Agreement State license is required (NRC91).

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APPENDIX C

DESCRIPTION OF NRC AND AGREEMENT STATE LICENSED ACTIVITIES

C.1 GENERAL

NRC assigns a five-digit program code number to each license to designate the major activity or principal use provided for in the license.[1] The regulations applicable to the various activities and uses of byproduct, source, and special nuclear materials are contained in Parts 30, 40 and 70, respectively, of Title 10 of the *Code of Federal Regulations* (CFR). A basic understanding of these regulations is a necessary prerequisite to the proper assignment of a program code to a particular activity or use. NRC uses about 100 program codes to classify the approximately 8,200 active licenses under its direct control. Some of these program codes narrowly define an activity, such as radiography, while other program codes have a wider scope. More than one code may apply to a given license. However, the primary code indicates the licensee's principal use of material. A secondary code may be used to indicate other significant uses.

"Broad" licenses are issued to large facilities having a more comprehensive radiological protection program. These licenses authorize possession of a wide variety of radioactive materials without having each radionuclide and authorization listed on the license. There are three types of broad licenses--Type A, Type B, and Type C. Most broad licenses are Type A. (For a clear understanding of these three types, see 10 CFR Part 33.)

Broad Type A licenses are issued pursuant to 10 CFR 33.13 and typically authorize possession of any byproduct material with an atomic number between 1 and 83, in any chemical or physical form. The maximum possession limit is usually specified both for the individual radionuclide and for the total activity of all radionuclides. These licensees must have a radiological safety officer and a committee that acts in the place of NRC to make day-to-day decisions about the program.

Broad Type B licenses are issued pursuant to 10 CFR 33.14 and authorize possession of a variety of radionuclides. The maximum possession limit is specified in 10 CFR 33.100, Schedule A, Column I. Broad Type B licensees must have a radiological safety officer and adequate administrative controls.

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[1] The program codes referred to are designated by NRC and may or may not be used by Agreement States.

Broad Type C licenses are issued pursuant to 10 CFR 33.15 and authorize possession of a variety of radionuclides. The maximum possession limit is specified in 10 CFR 33.100, Schedule A, Column II. Broad Type C licensees must have training and experience as specified in the regulations, and the licensee must have adequate administrative controls.

"Other" licenses are usually issued to smaller organizations requiring a more restrictive license. These licenses are usually more specific in identifying each radionuclide, the chemical and physical form, and the authorized activities and users.

The program codes are also used to indicate the inspection category and priority and fee categories. Materials licensing and inspection fee categories are described in 10 CFR Part 170.31. The fuel cycle facility inspection program is described in NRC Manual Chapter 2600 (MC 2600)(NRC90). The inspection frequency for the various procedures at these facilities is described in Table 1 of MC 2600. Inspection program categories and priorities for materials licenses are described in detail in NRC Manual Chapter 2800 (MC 2800) (NRC90a).

Initial inspection of licenses in categories with priorities 1 through 5 are conducted within 6 months after material is received and operations under the license have begun. Initial inspections of licenses in categories with priorities 6 and 7 are conducted within 1 year.

Routine, periodic inspections are normally conducted at intervals in years corresponding to the inspection priority for that category:

- Priority 1 - yearly
- Priority 2 - every two years
- Priority 3 - every three years
- Priority 4 - every four years
- Priority 5 - every five years
- Priority 6 or 7 - inspected initially and thereafter normally only for resolution of problems.

C.2 BYPRODUCT MATERIAL PROGRAM (10 CFR 30)

Byproduct materials are man-made radioactive materials (except special nuclear material - refer to Section C.5) produced or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear materials such as in a nuclear reactor. Byproduct material does include activation products from nuclear reactors and from plutonium-beryllium (Pu-Be) neutron sources, but does not include activation products from other neutron sources such as Cf-252 or accelerators.

Byproduct Material Licenses (10 CFR 30, 32, 33, & 35)

Byproduct Material Licenses are issued to educational institutions, medical facilities, industrial facilities, and individuals for the possession and use of byproduct materials and radionuclides for teaching, training, research and development, manufacturing, equipment calibration, medical research and development, medical diagnosis and/or therapy. There are many Byproduct Material Licenses categories, including Medical Private Practice Licenses, Well-Logging Licenses, Measuring Systems Licenses, Waste Disposal Services Licenses, General License Distribution Licenses, Exempt Distribution Licenses, Industrial Radiography Licenses, Irradiators Licenses, and Low Level Waste Storage Licenses, some of which do not have air emission concerns. Listed below are those licenses that are required to comply with regulatory limits on airborne radionuclide emission.

- Academic Broad and Academic Other - These licenses are issued to educational institutions for the possession and use of radionuclides for teaching, training and some research purposes, such as C-14 dating, equipment calibration, tracer studies, and the identification of substances in compounds.

- Medical Institution Broad & Medical Institution Other - A medical institution is defined in 10 CFR 35.2 to be an organization in which several medical disciplines are practiced. It typically provides 24-hour-per-day medical, surgical, or psychiatric treatment, nursing, food, and lodging to ill or injured patients. Medical Institution Broad and Medical Institution Limited licenses are issued to organizations for the application of byproduct material, or its radiation, to humans. Separate licenses are issued to authorize teletherapy. Radioactive material administered to patients is an in-vivo procedure.

- Medical Private Practice - These licenses are issued, pursuant to 10 CFR 35.12, to physician for the possession and use of radionuclides in well established diagnostic and therapeutic procedures usually in their offices outside a medical institution.

- Well Logging - Well-logging licenses are issued, pursuant to 10 CFR 39, to firms for the possession and use of radionuclides for subsurface surveying to obtain geological information. These testing procedures are primarily used in oil, gas, and mineral exploration to identify subsurface geologic formations.

- Measuring Systems - Measuring system licenses are issued for the possession and use of measuring devices such as gauges and gas chromatographs containing radionuclides. Frequently, the equipment is serviced and leak tested by the manufacturer or lessor of the equipment.

- Manufacturing and Distribution - These licenses are issued for the manufacture and distribution of products containing byproduct material in various forms for a number of diverse purposes. Licensees include medical suppliers that process, package and distribute products such as diagnostic test kits, radioactive surgical implants, and tagged radiochemicals for use in medical, academic and industrial research, and for diagnosis and therapy. Licensees are also suppliers who, after purchasing bulk quantities of byproduct material, process, encapsulate, package, and distribute these sealed sources for use in gamma radiography, cobalt irradiation, and well-logging. Firms are also involved with the manufacture, assembly, and distribution of various other products that contain radionuclides. The broad licenses are issued to the larger facilities having more comprehensive radiological protection programs.

- Waste Disposal Services - Waste disposal licenses authorize the collection, transportation, and storage of radioactive wastes. These licenses authorize firms to collect packaged waste material, transport the waste, and temporarily store it before transporting the waste to an authorized burial ground. Some licenses authorize the opening of packages and treatment of the waste to reduce the volume, e.g., compaction.

- General License Distribution - General license distribution licenses are issued for the distribution of byproduct material, usually sealed sources in devices, to general licensees. Examples of such devices are: gauges, luminous aircraft safety devices, calibration and reference sources, ice detection devices, and in vitro test kits. The requirements for a license for distribution to general licensees are specified in various sections of 10 CFR 32. A general licensee does not need to submit a formal application and does not receive a formal license. The conditions of a general license are described in 10 CFR 31.

- Exempt Distribution - Exempt distribution licenses are issued for the commercial distribution of byproduct material to persons who are exempt from the licensing requirements. These exemptions and their limitations, if any, are defined in 10 CFR 30.14-30.20. Examples of exempt items are: watches, balances, locks, compasses, electron tubes, synthetic plastic resin for sand consolidation, and smoke detectors. The requirements for a license to distribute byproduct material to persons exempt from licensing are presented in 10 CFR 32.

- Industrial Radiography - Industrial radiography licenses are issued for the possession and use of sealed radioactive materials, usually in exposure devices or "cameras," that emit gamma rays for nondestructive examination of pipelines, weld joints, steel structures, boilers, aircraft and ship parts, and other high-stress alloy parts. The radioisotopes most commonly used are Co-60 and Ir-192. Radiography can be conducted either in a permanent facility or at a temporary job site.

- Irradiators - Irradiator licenses are issued for the possession and use of high-activity sealed sources of radioactive material in an irradiator constructed so that the sealed sources and the material being irradiated are contained in a shielded volume. Primary uses include non-human medical and nonmedical research, conducted chiefly by universities, and industrial uses, such as the sterilization of medical products and drugs and treatment of hardwoods, plastics, and semi-conductor materials. The radioisotopes most commonly used in these irradiators are Co-60 and Cs-137. Self-shielded units are designed so that the operator cannot inadvertently place any part of his/her body in the path of the beam. Units other than self-shielded units may rely on facility alarms and interlocks to prevent accidental exposure to radiation. The "Irradiators Other" category includes units where the source is stored and/or used under water.

- Research and Development Licenses - These licenses are issued to private organizations, universities, and government agencies for the possession and use of radionuclides in research. Typical uses include: irradiation of materials, tracers and catalysts in chemical reactions, measurement using industrial gauges, and the identification of substances in compounds. In private industry, uses are primarily in product development. In academic institutions, research and development includes training of students in the use of radioactive materials. Broad licenses are issued to larger facilities having a more comprehensive radiation protection program where the types of research being conducted may change rapidly. Typical activities include environmental analysis, food quality studies, aerospace and engineering applications, and product development.

- Civil Defense - Civil defense licenses are issued for the possession and use of sealed sources for training individuals in civil defense activities, such as calibrating and demonstrating the use of radiation survey and monitoring equipment.

- Low-Level Waste Storage - Other - Licenses are issued to allow additional onsite storage of low-level radioactive waste generated on site.

C.3 SOURCE MATERIAL PROGRAM (10 CFR 40)

Source materials are materials essential to the production of special nuclear materials (refer to Section C.5). Source material includes: (1) uranium (and depleted uranium produced as enrichment tails) or thorium, or any combination thereof, in any physical or chemical form, or (2) ores that contain by weight one twentieth of one percent (0.05%) or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.

Source Material Licenses

Source Material Licenses are issued for the possession and use of refined uranium and/or thorium for fabrication, research, and manufacture of consumer products such as ceramics and glassware, manufacture of refractors, uranium shielding, analytical standards, and other uses not specifically classified. A smaller number of these licenses are issued to allow the possession of uranium and/or thorium for uses other than processing or fabrication

of any kind, such as distribution and storage. An even smaller number of these licenses are issued for the use of uranium in subcritical assemblies. The Source Material Licenses are divided into the following categories:

- Mills - These licenses are issued for the extraction of uranium from uranium ore. In milling operations, the ore is crushed, ground to fine mesh, and chemically treated to extract the uranium and convert it to a form called yellowcake.

- Source Material, Other, Less Than 150 Kilograms - These licenses are issued for the possession and use of source material for fabrication, research, or manufacture of consumer products. These licenses do not allow the possession of more than 150 kilograms of material.

- Source Material, Shielding - These licenses are issued for the possession and use of source material in shielding for protection against radiation.

- Source Material, Military Munitions Testing - These licenses are issued for the possession, use and testing of depleted uranium products designed for the military.

- Source Material, General License Distribution - These licenses are issued to authorize the initial transfer of industrial products and devices containing depleted uranium, or to allow the initial transfer of such products or devices to persons issued a general license under Part 40.25.

- Source Material, Other, Greater Than 150 Kilograms - These licenses are issued for the possession and use of source material for fabrication, research, or manufacture of consumer products. These licenses authorize the possession of more than 150 kilograms of material.

- Uranium Hexafluoride Production Plants - These licenses are issued for the possession and use of uranium to allow the conversion of yellowcake and/or ore concentrates to uranium hexafluoride (UF_6).

- Solution Mining - These licenses are issued for the extraction of uranium from uranium ores. The only mining operation licensed by NRC is solution mining, which is leaching of ore by injection of liquid chemicals into the geologic formation.

- Heap Leach, Ore Buying Stations and Byproduct Recovery - These licenses are issued for the recovery of source material from low-grade uranium ores, from old tailings piles, or from a small ore body at a location distant from a mill complex. The heap leach process consists of spraying or trickling an acid dilution over sections of the heap pile. Pipes or covered drains in the base of the pile collect the uranium-enriched solution after it percolates through the heap.

- Rare Earth Extraction and Processing - These licenses are issued for the possession and use of source material for processing activities not directly related to the nuclear fuel cycle. This category includes licenses for extraction of metals, heavy metals, and rare earths.

- Source Material Licenses - These licenses are issued for the possession and use of source material for miscellaneous activities including licenses for sites that once processed source material but are now being decommissioned. Some sites include disposal areas, such as tailings or slag piles. Licenses for these sites are issued for possession and storage only.

C.4 RESEARCH AND TEST REACTOR PROGRAM (10 CFR 50, TYPE 104)

Research and test reactors include those used in medical therapy and research and development facilities. The latter means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

C.5 SPECIAL NUCLEAR MATERIAL PROGRAM (10 CFR 70)

Special nuclear materials include plutonium, U-233, uranium enriched in the isotopes of U-233 or U-235, and any material artificially enriched in any of these materials.

Special Nuclear Material Licenses

Special Nuclear Material licenses are issued to licensees to receive, own, acquire, deliver, possess, use, and initially transfer special nuclear material. These licenses are divided into the following categories:

- Hot Cell Operations - These licenses are issued for the processing and fabrication of reactor fuels containing uranium and/or plutonium for experimental purposes. Some facilities also perform chemical operations to recover the uranium and plutonium from scrap and other off-specifications materials.

- Decommissioning of Advanced Fuel R&D and Pilot Plants - These licenses are issued to facilities which has notified NRC of their intent to terminate a portion or all of their activities involving special nuclear material and/or have submitted to NRC a plan and schedule for the facilities, property, and equipment so that they may be released for unrestricted use.

- Uranium Enrichment Plants - Uranium enrichment plant licenses are issued for the possession and use of source and special nuclear material for the purpose of enriching natural uranium in the U-235 isotope. Existing and planned plants enrich uranium in the form of uranium hexafluoride, either by gaseous diffusion or gas centrifuge methods. Future plants may use other forms of uranium and methods of enrichment. Plants whose product is for eventual use in commercial power reactors enrich uranium up to about 5 percent U-235, while plants whose product is for naval reactor propulsion enrich uranium to greater than 90 percent U-235.

- Uranium Fuel Fabrication Plants - These licenses are issued for the possession and use of special nuclear material for the purpose of fabricating uranium fuel elements. In most uranium facilities where light water reactor fuels are processed, low-enriched uranium hexafluoride is converted to uranium dioxide pellets and inserted into zirconium tubes. The tubes are fabricated into fuel assemblies which are shipped to commercial nuclear power plants. In other facilities, high-enriched uranium is processed into naval reactor fuel and fabricated into naval reactor cores or core components. Licenses are for possession and use of 5 kilograms or more of U-235 that has been enriched to less than 20 percent.

- Decommissioning of Uranium Fuel Fabrication Plants - These licenses are issued to facilities that have notified NRC of their intent to terminate a portion or all of their activities involving special nuclear material and/or has submitted to NRC a plan and schedule for the facilities, property, and equipment so that they may be released for unrestricted use.

- Uranium Fuel Research and Development and Pilot Plants - These licenses are issued for the possession and use of enriched uranium for purposes such as academic training and in research and development activities associated with nuclear fuel other than fuel processing. Licenses authorize possession and use of 5 kilograms or more of enriched U-235 in unsealed form, or 2 kilograms or more of U-233 in unsealed form.

- Critical Mass Material - These licenses are issued for the possession and use of special nuclear material in quantities sufficient to form a critical mass, specifically, more than 350 grams of enriched U-235, more than 200 grams of U-233, more than 200 grams of plutonium, or any combination thereof.

- Decommissioning of Critical Mass - Other Than Universities - These licenses are issued to facilities that have notified NRC of their intent to terminate a portion or all their its activities involving special nuclear material and/or has submitted to NRC a plan and schedule for the facilities, property, and equipment so that they may be released for unrestricted use.

- Special Nuclear Material, Plutonium-Unsealed, Less Than a Critical Mass - These licenses are issued for the possession and use of small quantities of plutonium (less than 200 grams total) in unsealed form for purposes such as biological and chemical testing and for calibration of instruments.

- Special Nuclear Material, U-235 and/or U-233 Unsealed, Less Than a Critical Mass - These licenses are issued for the possession and use of small quantities of uranium (less than 350 grams of U-235 and/or less than 200 grams of U-233) in unsealed form for purposes such as biological and chemical testing and for calibration of instruments.

- Special Nuclear Material, Plutonium Neutron Sources, Less Than 200 Grams - These licenses are issued for the possession and use of small quantities of plutonium (less than 200 grams total) usually combined with beryllium as the source of neutrons for instrument calibration, teaching and demonstration purposes, and industrial applications.

- Power Source with Byproduct and/or Special Nuclear Material- These licenses are issued for the possession and use of byproduct and/or special nuclear material to generate heat or power that will be used in remote weather stations, space satellites, and other special applications.

- Special Nuclear Material Plutonium - Sealed Source in Devices - These licenses are issued for the possession and use of sealed sources containing special nuclear material installed in devices such as gauges.

- Special Nuclear Material Plutonium - Sealed Source Less Than a Critical Mass - These licenses are issued for the possession and use of small quantities of plutonium (less than 200 grams total) in sealed sources for purposes such as biological and chemical testing and for calibration of instruments, etc.

- Special Nuclear Material, U-235 and/or U-233 - Sealed Source Less Than a Critical Mass - These licenses are issued for the possession and use of small quantities of uranium (less than 350 grams of U-235 and/or less than 200 grams of U-233) in sealed sources for purposes such as biological and chemical testing and for calibration of instruments, etc.

- Pacemaker - Byproduct Material and/or Special Nuclear Material - These licenses are issued to: (1) medical facilities for the surgical implantation of pacemakers that are powered by a device containing byproduct or special nuclear material;
(2) manufacturers and distributors for the distribution of these pacemakers; and
(3) individuals, most often Canadian citizens on holiday, with implanted nuclear pacemakers who are visiting in the United States.

- Special Nuclear Material, General License Distribution - These licenses are issued to individuals for the initial distribution of calibration or reference sources containing plutonium to persons who have been issued a general license under Part 70.19. General licenses under Part 70.19 authorize the possession and use of plutonium in calibration or reference sources. A person may be a general licensee only if the person is already a specific licensee.

- Fresh Fuel Storage at Reactor Sites - These licenses are issued to commercial nuclear power reactors that have been granted a Construction Permit (CP) but not an Operating License (OL). These licenses authorize the storage of new unirradiated reactor fuel elements containing special nuclear material. Once a reactor has been granted an OL, this Part 70 materials license is terminated. (The OL includes authorization for the possession of the fuel.)

- Interim Spent Fuel Storage - These licenses are issued under 10 CFR Part 72 for possession of power reactor spent fuel and other radioactive materials associated with spent fuel storage, in an independent spent fuel storage installation. (These licenses are issued for up to 20 years.)

- Transport - Private Carriage - Transport-Private Carriage licenses are issued for the possession of byproduct, source, and special nuclear materials in packages authorized under Part 71, and in private carriage from a carrier's terminal to the licensee's facility, all within the United States.

C.6 REFERENCES

NRC90 U.S. Nuclear Regulatory Commission, "NRC Inspection Manual, Chapter 2600, Fuel Cycle Facility Operational Safety Inspection Program," March 1990.

NRC90a U.S. Nuclear Regulatory Commission, "NRC Inspection Manual, Chapter 2800, Materials Inspection Program," April 1990.

NRC91 U.S. Nuclear Regulatory Commission, "Program Code Descriptions Used In NRC Licensing and Inspection Programs," January 1991.

APPENDIX D

DESCRIPTION OF FACILITIES EVALUATED

This appendix describes the types of facilities other than nuclear power reactors, licensed by NRC and Agreement States, whose radioactive effluents were evaluated for the purpose of conducting the NESHAPs rulemaking.

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APPENDIX D

DESCRIPTION OF FACILITIES EVALUATED

The NESHAP applies to approximately 8,000 NRC-licensed and non-DOE federal facilities other than nuclear power reactors that possess unsealed sources of radioactive materials. NRC-licensed facilities other than nuclear power reactors include material licensees, non-power reactor licensees, and facilities engaged in the uranium fuel cycle. NRC-licensed facilities other than nuclear power reactors also include facilities licensed by the Agreement States but exclude low-energy accelerators and facilities regulated under 40 CFR Part 191, Subpart B. Pertinent information regarding the facility types considered for evaluation, including those where further study was not warranted, is listed in Table D-1.

The major types of facilities covered by the standard are described in the following sections. The discussion focuses on the physical forms of the radionuclides used and the handling and processing that the materials undergo. These factors are major determinants of the quantities of materials handled that become airborne.

The descriptions provided below were obtained from the Nuclear Regulatory Commission's public document room(s), supplemented as necessary by "EPA's Environmental Impact Statement, NESHAPs for Radionuclides, Background Information Document - Volume 2," dated September 1989, and "Background Information Document - Procedures Approved for Demonstrating Compliance with 40 CFR Part 61, Subpart I," dated October 1989.

D.1 BYPRODUCT MATERIAL LICENSEES (10 CFR 30)

D.1.1 Users and Producers of Radionuclides for Medical Purposes

The users and producers of radioactive materials for medical purposes constitute by far the largest category of facilities handling unsealed radioactive sources. Approximately two-thirds of the 8,000 facilities covered by the NESHAP are engaged in some aspect of the production and distribution of radiopharmaceuticals or in the medical application of these materials. Medical uses of radiopharmaceuticals include biomedical research and patient administration of radiopharmaceuticals for both diagnostic and therapeutic purposes.

Table D-1. NRC licensees other than power reactors.

A. NRC-LICENSEES COVERED BY THE RANDOM SURVEY[1]		
PROGRAM CODE	PROGRAM CODE DESCRIPTION	NUMBER OF ACTIVE LICENSEES
01100	Academic Type A	44
01110	Academic Type B	14
01120	Academic Type C	19
01200	Academic Other	0
02110	Medical Institution Broad	121
02120	Medical Institution Limited	1384
02121	Medical Institution Custom	14
02200	Medical Private Practice Limited	306
02201	Medical Private Practice Custom	165
02209	Grandfathered In-Vivo General Medical Use	69
02220	Mobile Nuclear Medicine Service	22
02400	Vet, Non-Human	4
02410	In-Vitro Testlab	124
02500	Nuclear Pharmacies	50
02511	Medical Product Distribution - 32.72	3
02512	Medical Product Distribution - 32.73	7
02513	Medical Product Distribution - 32.74	6
03211	Manufacturing/Distribution Broad Type A	18
03212	Manufacturing/Distribution Broad Type B	17
03213	Manufacturing/Distribution Broad Type C	3
03214	Manufacturing/Distribution Other	134
03218	Nuclear Laundry	5
03232	Waste Disposal Service Prepackaged Only	7
03234	Waste Disposal Service Processing/Repackaging	7
03610	Research and Development Broad Type A	130
03611	Research and Development Broad Type B	13
03612	Research and Development Broad Type C	21
03613	Research and Development Broad -Multisite-Multiregional	3
03620	Research and Development Other	561
11200	Source Material Other <150kg	26
11210	Source Material Shielding	44
11230	Source Material General License Distribution	0
11300	Source Material Other > 150 k	84
11500	Solution Mining (R&D and Commercial Facilities)	9
11600	Heap Leach, Ore Buying Stations & Byproduct Recovery	3
11800	Source Material	4
21130	Hot Cell Operations	5
21135	Decommissioning Uranium Fuel R&D & Pilot Plants	2
21215	Decommissioning Uranium Fuel Processing Plants	3
21240	Uranium Fuel R&D and Pilot Plants	1

Table D-1. NRC licensees other than power reactors (continued).

A. NRC-LICENSEES COVERED BY THE RANDOM SURVEY[1]		
PROGRAM CODE	PROGRAM CODE DESCRIPTION	NUMBER OF ACTIVE LICENSEES
21310	Critical Mass Material for Universities	10
21320	Critical Mass Material Except Universities	4
21325	Decommissioning Critical Mass Except Universities	0
22110	Special Nuclear Material, Unsealed Plutonium < 200g	16
22111	Special Nuclear Material, Unsealed U-235 < 350g, U-233 < 200g	12
22170	Special Nuclear, General License Distribution	0
25110	Transport - Private Carriage	2
	Miscellaneous	13
	SUBTOTAL	3,509

[1] 10 CFR 50 licensees (reactors and test/research reactors) were not part of the data base used to select the random sample. Other source categories were deleted from the data base whenever (1) EPA had a specific interest in studying that source category (e.g., rare earth processors), or (2) due to their small numbers, there was no guarantee that the source category would show up in the random selection (e.g., low-level radioactive waste disposal facilities).

B. NRC-LICENSEES INCLUDED IN THE DESIGNATED SURVEY - PRIOR EVALUATIONS UPDATED AND NEW SOURCE CATEGORIES ADDED[2]		
PROGRAM CODE	PROGRAM CODE DESCRIPTION	NUMBER OF ACTIVE LICENSEES
	Test and Research Reactors	70
03231	Waste Disposal - Burial	2
03233	Waste Disposal Service - Incineration	1
03235	Incineration, Non-Commercial	0
06100	Low Level Waste Storage	0
11100	Mills	20
11220	Source Material Military Munitions Testing	9
11400	Uranium Hexaflouride Production Plants	2
11700	Rare Earth Extraction and Processing	11
21210	Uranium Fuel Processing Plants	11
	SUBTOTAL	126

[2] The designated facility data base consists of (1) specific facilities (e.g., large hospitals) EPA has evaluated in prior studies and in need of updating (e.g., site-specific demographics), and (2) specific facilities in which EPA has developed an interest (e.g., rare earth processors).

Table D-1. NRC licensees other than power reactors (continued).

C. NRC-LICENSEES EXCLUDED FROM THE RANDOM SURVEY AND DESIGNATED SURVEY - SEALED SOURCES[3]		
PROGRAM CODE	PROGRAM CODE DESCRIPTION	NUMBER OF ACTIVE LICENSEES
02210	Eye Applicators Sr-90	50
02300	Teletherapy	223
03110	Well-Logging Byproduct and/or SNM Tracer and Sealed Sources	45
03111	Well-Logging Byproduct and/or SNM Sealed Sources	54
03112	Well Logging Byproduct Only - Tracers Only	6
03113	Field Flooding Studies	4
03120	Measuring Systems Fixed Gauges	772
03121	Measuring Systems Portable Gauges	1,529
03122	Measuring Systems Analytical Instruments	112
03123	Measuring Systems Gas Chromatographs	596
03124	Measuring Systems Other	83
03220	Leak Test Service Only	10
03221	Instrument Calibration Service Only, Source < 100 Curies	48
03222	Instrument Calibration Service Only, Source > 100 Curies	19
03223	Leak Test & Instrument Calibration Service, Source < 100 Curies	18
03224	Leak Test & Instrument Calibration Service, Source > 100 Curies	5
03225	Other Services	70
03240	General License Distribution - 32.51	49
03241	General License Distribution - 32.53	1
03242	General License Distribution - 32.57	1
03243	General License Distribution - 32.61	0
03244	General License Distribution - 32.71	33
03250	Exempt Distribution - Exempt Concentrations and Items	6
03251	Exempt Distribution - Certain Items	63
03252	Exempt Distribution - Resins	0
03253	Exempt Distribution - Small Quantities	45
03254	Exempt Distribution - Self Luminous Products	13
03255	Exempt Distribution - Smoke Detectors	26
03310	Industrial Radiography Fixed Location	64
03320	Industrial Radiography Temporary Job Sites	192
03510	Irradiators Self Shielded < 10,000 Curies	172
03511	Irradiators Other < 10,000 Curies	19
03520	Irradiators Self Shielded > 10,000 Curies	33
03521	Irradiators Other > 10,000 Curies	20
03710	Civil Defense	30
22120	Special Nuclear Material, Plutonium Neutron Sources, <200g	92

Table D-1. NRC licensees other than power reactors (continued).

C. NRC-LICENSEES EXCLUDED FROM THE RANDOM SURVEY AND DESIGNATED SURVEY - SEALED SOURCES[3]		
PROGRAM CODE	PROGRAM CODE DESCRIPTION	NUMBER OF ACTIVE LICENSEES
22130	Power Sources with Byproduct and/or Special Nuclear Material	0
22140	Special Nuclear, Plutonium Sealed Source in Devices	10
22150 22151	Special Nuclear, Plutonium Sealed Sources, < Critical Mass Special Nuclear, U-235, U-233 Sealed Sources, < Critical Mass	15 3
22160 22161 22162	Pacemaker Byproduct/Special Nuclear - Medical Institution Pacemaker Byproduct/Special Nuclear - Individual Pacemaker Byproduct/Special Nuclear - Manufacturing & Distribution	68 4 1
23100	Fresh Fuel Storage at Reactor Sites	5
	SUBTOTAL	4,609
	TOTAL	8,244

[3] Sealed source users are excluded from the Random Survey and Designated Survey data bases because the potential for airborne radioactive effluents is essentially zero.

Radiopharmaceutical Users

The types of facilities that use radionuclides for medical purposes include hospitals, clinics, and biomedical research facilities. The radionuclides used directly in patient therapy and diagnosis are termed "radiopharmaceuticals," while those used in research are referred to as "radionuclides." For simplicity, the term "radiopharmaceuticals" will be used to refer to the radioactive materials used in both patient administration and research.

The radiopharmaceuticals used at medical facilities occur in all three basic physical states: solid, liquid, and gas. The physical state of a particular radiopharmaceutical product is determined by (1) the chemical form of the radionuclide and (2) the solution or other mixture, if any, in which the radionuclide is dispensed. Both the radionuclide and the substance in which it is mixed are chosen to suit specific therapeutic, diagnostic, and research purposes.

The mixing of the radionuclide with some other substance means that the physical state of a radiopharmaceutical product may be different than the physical state of the radionuclide itself. In this document, discussions of the form of a particular radionuclide refer to the radionuclide product. The physical states of these products are important in assessing the potential for airborne release.

Most radionuclides used in medical facilities occur in liquid form. These liquids may be administered either orally or intravenously. Orally administered radionuclides are usually in the form of aqueous solutions. Many of these chemicals are ionic salts and thus occur in liquid form as saline solutions. Radionuclides that are administered intravenously may occur as solutions, colloids, or suspensions.

Solutions consist of molecules of solids or gaseous substances dissolved in a liquid. Colloids involve the dispersion of larger particles (on the order of 10 nanometers to 1 micrometer in diameter) in a liquid medium; the larger particles are prevented from aggregating and settling by being coated with a layer of gelatin (as is done with Au-198). Suspensions are similar to colloids but involve the radionuclide labeling of still larger particles (greater than 10 micrometers in diameter) of substances such as human serum albumin.

Gaseous radionuclides usually occur naturally in elemental form (e.g., Xe-133), and are administered to patients as a pure gas or as a gas diluted by air. Patients normally inhale the gas from a bag or from a gas "generator" through a respirator.

Solid radionuclides occur as gelatin capsules containing liquid solutions of the radionuclide chemical. In some cases, the solution is absorbed in dry filler material. Solid radionuclides are administered orally to patients.

The number of radionuclides with medical applications is extensive and increasing. In the areas of diagnosis and therapy, the most commonly used radiopharmaceuticals include Cr-51; Co-57, -58, and -60; Ga-67 and -68; Tc-99m; I-123, -125, and -131; Se-75, Xe-127 and -133; and Tl-201. Biomedical researchers employ tritium, C-14, P-32, and S-35 extensively. The radiopharmaceuticals used in medical applications may be obtained from radiopharmaceutical manufacturers or independent radiopharmacies, or they may be produced on site from radiopharmaceutical generators. Because of the relatively short half-lives of the

radionuclides used in medicine, shipments from vendors are received frequently (weekly or daily), and storage times are minimal.

Radiopharmaceuticals purchased from vendors may be in the form of pre-packaged dose kits, radiopharmaceutical generators, or bulk supplies from which individual doses are extracted and prepared. Handling of prepackaged dose kits may involve no more than removing the material from the package and administering the radiopharmaceutical to the patient either orally or by intravenous injection.

Handling of materials obtained in the form of bulk stocks or radiopharmaceutical generators is more involved. In general, these materials are received and stored in a central area where individual doses are prepared. In the case of liquids, dose preparation involves extracting the required quantity from the stock solution by syringe or pipette and diluting the material in a suitable sterile medium. These operations are conducted in a fume hood, and the dose is administered to the patient either intravenously or orally.

Preparation of doses from radiopharmaceutical generators, of which Mo-99/Tc-99m generators are the most common, involves elution of the product from the generator and division of the elute into individual doses. The procedures for eluting a generator depend on whether it is a wet or dry column design. In a wet column generator, an evacuated extraction vial is attached to the end of the generator column with a sterile needle. Using the vacuum within the vial, the solvent is pulled from the generator reservoir through the column and into the vial. The procedure for a dry column generator is similar. However, since dry generators do not have a reservoir of solvent, solvent must be added to the column prior to elution. The charge vial is attached to one end of the generator, and then the evacuated extraction vial is attached to the other end. The solution is drawn through the generator column and collected in the elution vial. These elution procedures and dose divisions are conducted in a fume hood, with the generator shielded to prevent external irradiation of the technicians.

Handling of radionuclides for biomedical research is more varied than that of radiopharmaceuticals used for patient administration. Depending on the specific radionuclides used and the goal of the experiment, the materials may simply be extracted from bulk stocks and administered, or the radionuclide may be subjected to additional chemical or physical processing.

Radiopharmaceutical Producers and Suppliers

Radiopharmaceutical manufacturers produce the radionuclide-labeled compounds, diagnostic kits, and radionuclide generators used in biomedical research and medical diagnosis and therapy. The radiopharmaceutical products may be shipped directly to medical users, or they may be shipped to independent radiopharmacies where individual doses are prepared from the bulk supplies or generators and distributed to medical users. Individual radiopharmaceutical manufacturers may specialize in only a few widely used radiopharmaceuticals or may produce many of the radionuclides used in biomedical research and patient diagnosis and therapy.

The radionuclides used in radiopharmaceuticals are produced either in nuclear reactors or in accelerators. Radiopharmaceutical manufacturers may operate their own production facilities or may purchase the bulk radionuclides from an outside vendor. In producing the bulk radionuclides, a suitable target is first prepared and then bombarded with neutrons or positive ions in the reactor core or accelerator. Once irradiation is complete, the target is removed from the production device, and the product is recovered and purified in a hot cell by appropriate chemical processing.

The production of the labeled compounds used in radiopharmaceuticals and biomedical research is essentially a wet chemistry process. Depending on the specific radiopharmaceutical, workers conduct these operations within laboratory fume hoods or gloveboxes. The final products are generally assembled and packaged in assembly line operations.

Radiopharmaceutical generators are designed and produced as closed aseptic systems using some type of chromatographic column. Typically, this chromatographic column consists of an inorganic ion exchange resin to which the generator (parent) radionuclide is bound. As the parent radionuclide decays, the decay product, which has different chemical/physical properties, is produced. The decay product is eluted from the column by the user at specified intervals. Generators are manufactured in a hot cell, where the parent radionuclide is packed in the column, and the column of the generator is surrounded by absorbent materials and shielding. The absorbent materials minimize the consequences of accidental breakage; the shielding reduces the radiation exposure of users. Once the generator is loaded, final assembly and packaging are carried out on an assembly line.

Independent radiopharmacies are a relatively recent phenomenon. Generally located in large cities, these facilities serve as distribution facilities. Radiopharmacies purchase bulk stocks and generators from radiopharmaceutical manufacturers and provide hospitals and clinics with individually prepared doses on an as-needed basis. The dose preparation procedures at these facilities do not differ from those at medical facilities that obtain their radiopharmaceuticals directly from the manufacturers.

D.1.2 Sealed Source Manufacturers

Manufacture of Self-Illuminating Devices

While facilities that use only sealed radiation sources are not covered by the NESHAP, the industrial facilities that produce sealed sources are subject to the standard. The facilities in this category fall into two broad classes: those that manufacture encapsulated alpha-, beta-, or gamma-emitting radiation sources and those that manufacture self-luminous devices. Only the latter is included as part of the Designated Survey.

Self-illuminating devices include watches, compasses, signs, and aircraft instrumentation. Historically, Ra-226 was used in radio-luminescent products. However, the well-documented hazards of working with radium and the advent of other materials with inherently superior characteristics have largely eliminated the use of radium. Today, tritium and, to a much lesser extent, Kr-85 and Pm-147 are used in the production of self-luminous devices.

Two general types of self-illuminating devices are made: those in which the radio-luminous material is incorporated into a paint which is used to coat the dial and/or instrument hands; and those in which a radioactive gas (tritium or krypton) is contained in a phosphor-coated glass ampule. Only the second type is included as part of the Designated Survey.

Manufacturers of self-illuminating devices obtain the bulk radionuclides in either gaseous or (rarely) liquid form from a vendor. In the case of self-illuminating sources, the gaseous radionuclide (tritium or Kr-85) is transferred to a glass ampule and sealed. The process is carried out in areas with high ventilation rates or in fume hoods to protect the workers.

D.1.3 Waste Receivers-Shippers and Disposal Facilities

Low-Level Radioactive Waste Processing and/or Packaging

The radioactive wastes generated by facilities that use radionuclides must be disposed of in an approved manner. In general, wastes with high specific activities (such as uranium-contaminated scrap at non-oxide fuel fabrication facilities) will be recycled and recovered. However, virtually every user of unsealed radioactive materials will generate solid, low-level radioactive wastes which require active disposal. Such wastes may be incinerated on site or packaged and shipped off site to a licensed low-level waste disposal facility. This study investigated incinerators and packing facilities.

Waste receivers and shippers (sometimes called "waste brokers") are primarily collection and shipping agents for facilities generating low-level wastes. Most such receiving-shipping facilities simply collect the wastes in shipping containers approved by the Department of Transportation from a number of waste generating facilities, monitor the packages for contamination, and hold the wastes at a warehouse until they arrange a shipment to a licensed disposal site. The licenses of most such receiving and shipping facilities do not allow the facility to repack or even open the waste packages. However, several such facilities have been licensed to open, compact, and repackage waste materials before shipment.

Incineration

Recently, a new low-level waste operation called incineration has been established. Waste incinerators provide a volume reduction service by processing waste in the form of paper, plastic, metal, liquid, or animal carcasses. Most of the radioactivity projected to be burned is called dry active waste (DAW) from nuclear power plants. Much of the remainder is industry and institutional DAW. The retaining most radionuclides is immobilized and packaged for disposal. Some amount of radioactive material is discharged from the stack. Burning waste can reduce volume by as much as 95 percent.

Disposal

Until recently, low-level waste disposal in the United States was accomplished via "shallow land burial," a method that does not rely on engineered barriers to isolate the waste. Over the years several problems have developed and resulted in the closing of three of the six operating facilities. New federal and state laws require for future facilities that engineered barriers be used in addition to good siting practices. Some states have required a design goal of zero release.

A low-level radioactive waste disposal facility has two distinct phases of operation, pre-closure and post-closure. During the pre-closure phase, waste is received onsite, re-packaged if necessary, and placed in its final resting place. In the post-closure phase, monitoring of the facility is continued for a period of years into the future until institutional controls can no longer be assumed to be available, usually 100 years.

D.2 NON-POWER REACTOR LICENSEES (10 CFR 50, TYPE 104)

D.2.1 Test and Research Reactors

NRC licenses approximately 70 academic, research, and industrial facilities to operate test and research reactors. Test and research reactors are used as teaching devices, to study reactor designs, to conduct research on the effects of radiation on materials, and to produce radioactive materials used by sealed source and radiopharmaceutical manufacturers.

The design of such reactors and their sizes vary widely. Approximately 15 research reactors are used primarily as teaching devices and have very low power outputs (less than 15 watts). The nuclear cores of these reactors have their uranium fuel dispersed and fixed in a plastic matrix. Given the design and use of these teaching reactors, airborne releases cannot occur during normal operations.

Research and test reactors used for experimental and production purposes include both light-water pool and heavy-water tank-type designs, ranging in power from 100 kilowatts to 10 megawatts. All of these facilities use highly enriched uranium fuel, either in metal or mixed carbide fuel elements.

In these reactors, experiments and/or production activities are conducted by remotely inserting the target containing the material to be irradiated into the experimental ports or beam holes that penetrate the reactor core. The target material is subjected to the neutron flux of the reactor core for an appropriate period of time and then withdrawn via shielded transport devices (called "rabbit systems") to a hot cell. The irradiated material is examined or the product is recovered in the hot cell. Product recovery may be as simple as dissolving a soluble salt in water, or it may involve evaporation, precipitation, extraction, distillation, and/or ion exchange.

Potential airborne releases from such facilities include the fission products in the core of the reactor, activation products generated during the operation of the reactor, and releases from the disassembly and recovery of target materials in the hot cell.

In general, the activation products, along with any gaseous fission products escaping the coolant, are released directly to the atmosphere from the facility exhaust. Materials that become airborne during processing in the hot cell will be vented through the hot cell's exhaust system. The effluent from the hot cell is generally filtered through high efficiency particulate air (HEPA) filters before release.

D.3 URANIUM FUEL CYCLE FACILITIES (10 CFR 40 and 70)

The uranium fuel cycle includes uranium mills, uranium hexafluoride conversion facilities, uranium enrichment facilities, light-water reactor fuel fabricators, light-water power reactors, and fuel reprocessing plants. With the exception of the uranium enrichment facilities that are owned by the federal government and operated by contractors under the supervision of the Department of Energy (DOE), these facilities are licensed by NRC or the Agreement States. Nuclear power reactors and DOE enrichment facilities are not part of this study.

D.3.1 Source Material Licensees (10 CFR 40)

Uranium Mills

Uranium mills extract uranium from ores which contain only 0.01 to 0.3 percent U_3O_8. Uranium mills, typically located near uranium mines in the western United States, are

usually in areas of low population density. The product of the mills is shipped to conversion plants, where it is converted to volatile uranium hexafluoride (UF_6) which is used as feed to uranium enrichment plants.

As of December 1988, of 27 uranium mills in the United States licensed by NRC or the Agreement States, 4 were operating, 8 were shut down, 14 were being decommissioned, and 1 had been built but never operated. The eight shut down mills could resume operations, but the 14 mills that are being decommissioned will never operate again.

The operating mills have a capacity of 9,600 tons of ore per day. The number of operating mills is down considerably from 1981, when 21 mills were processing approximately 50,000 tons of ore per day. This reduction reflects the decrease in the demand for yellowcake. The mined ore is stored on pads prior to processing. Crushing and grinding and a chemical leaching process separate the uranium from the ore. The uranium product is dried and packaged following recovery from the leach solution. The waste product (mill tailings) is piped as a slurry to a surface impoundment area (tailings pile).

Radioactive materials released to the air during these operations include natural uranium and thorium and their respective decay products (e.g., radium, lead, radon). These radionuclides, with the exception of radon, are released as particulates.

Depleted Uranium Munitions Testing Facilities

The processing of natural uranium to obtain uranium enriched in the U-235 isotope results in abundant tails referred to as depleted uranium. Its ownership, possession, and use is licensed by NRC as source material. The density and low specific activity of depleted uranium make it useful for several applications, including radiological shielding, counterweights in aircraft, and in military munitions. This latter activity has the greatest potential to result in airborne release of radioactive material.

Depleted uranium is used by the military in munitions designed to pierce armor plating. The design of these munitions is developed and refined by the army based on "soft" and "hard" testing. Soft testing is conducted to define and refine the accuracy of the munitions, and is conducted on outdoor firing ranges where the depleted uranium round is fired at the "target" located in a sand-filled testing enclosure located several kilometers from

the gun. After impact, the depleted uranium "rod," which is generally intact, is simply left in the ground as the risk from unexploded munitions makes retrieval too dangerous. Hard testing is conducted to evaluate and refine the destructive capability of the munitions. In hard testing, either actual munitions or scale mockups are fired at an armor-plated target. By license conditions, all hard testing of depleted uranium munitions is conducted in indoor test enclosures, the ventilation stacks of which are equipped with roughing and HEPA filters; the exhaust is monitored during testing.

The Department of Defense conducts testing of depleted uranium munitions at a number of proving grounds around the country. The U.S. Department of the Army's Ballistic Research Laboratory and Combat Systems Test Activity facilities at the Aberdeen Proving Ground in Aberdeen, Maryland conduct both hard and soft testing. Soft testing is also conducted by the Army at the Yuma Proving Ground near Yuma, Arizona, and at the Jefferson Proving Ground near Madison, Indiana, and the Navy conducts soft test firings at the China Lake Weapons Testing Site near China Lake, California. Occasionally, on the order of once every two or three years, the Army conducts an open-air hard test firing at the Nevada Test Site. These munitions are used only during actual hostilities, not during training or exercises.

Uranium Conversion Facilities

The uranium conversion facility purifies and converts uranium oxide (U_3O_8 or yellowcake) to volatile uranium hexafluoride (UF_6),the chemical form in which uranium enters the enrichment plant.

Currently 2 commercial uranium hexafluoride (UF_6) production facilities are operating in the United States: the Allied Chemical Corporation facility at Metropolis, Illinois and the Kerr-McGee Nuclear Corporation facility at Sequoyah, Oklahoma. The Allied Corporation facility, a dry-process plant in operation since 1968, has a capacity to produce about 12,600 mt of uranium per year in the form of UF_6. The Kerr-McGee Nuclear Corporation facility is a wet-process plant in operation since 1970, with a capacity of about 9,100 mt per year.[1]

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[1] U.S. Atomic Energy Commission, Fuels and Materials Directorate of Licensing, Environmental Survey of the Uranium Fuel Cycle, April 1984, and W. Dolezal, personal communication with D. Goldin, SC&A, Inc., September 1988.

Two industrial processes are used for uranium hexafluoride production, the dry hydrofluor method and the wet solvent extraction method. Each method produces roughly equal quantities of uranium hexafluoride; however, the radioactive effluents from the two processes differ substantially. The hydrofluor method releases radioactivity primarily in the gaseous and solid states, while the solvent extraction method releases most of its radioactive wastes dissolved in liquid effluents.

- Dry Hydrofluor Process

This process consists of reduction, hydrofluorination, and fluorination of concentrated ore to produce crude uranium hexafluoride. Fractional distillation is used to obtain purified UF_6. Impurities are separated either as volatile compounds or as a relatively concentrated and insoluble solid waste that is dried and drummed for disposal.

- Solvent Extraction Process

The solvent extraction process employs a wet chemical solvent extraction step at the start of the process to prepare high purity uranium for the subsequent reduction, hydrofluorination, and fluorination steps. The wet solvent extraction method separates impurities by extracting the uranium from the organic solvent, leaving the impurities dissolved in an aqueous solution. The raffinate is impounded in ponds at the plant site.

Rare Earth Extraction and Processing Facilities

Rare-earth elements are metals with distinct individual properties which make them potentially valuable as alloying agents. The name rare earths is deceiving, however, because they are neither rare nor earths. Rare earth minerals exist in many parts of the world, and the overall potential supply is essentially unlimited. The term earth stems from the fact that the elements were first isolated from their ores in the chemical form of oxides and that the old chemical terminology for oxide is earth. The rare earths (also called Lanthanides) form trivalent bonds, and when their salts are dissolved in water, they ionize to form trivalent ions and the solutions exhibit very similar chemical properties, sharing a valence of three. Rare earths are widely distributed in nature, although they generally occur in low concentrations.

Approximately 10 facilities are engaged in the recovery of metals from source materials. Rare earth facilities with NRC Source Material Licenses process natural and synthetic ores which contain at least 0.05 percent, by weight, of naturally occurring uranium and thorium. The principal environmental impacts of rare earth facility operations include the potential release of radioactive particles and radon from the storage, handling, and processing of the ores. The operation of a rare earth facility involves grinding, dissolving, and processing the natural and synthetic ores. The ores are fed into a grinding machine where they are reduced into particle size. Dust from this process goes to a dust collector which recycles the dust back into the system, scrubs it, then releases it into the environment. Because this process is relatively closed, it is generally believed that very limited amounts of radioactivity escape. The reduced ores are transferred through pipes into digester tanks which contain acid that selectively dissolves the ores. The unwanted uranium and thorium react with the acid to form insoluble uranium and thorium fluorides. Different facilities have different processes by which they store the radioactive wastes. It is often stored onsite in barrels or slag piles.

D.3.2 Special Nuclear Material Licensees (10 CFR 70)

LWR Fuel Fabrication Facilities

Light water reactor (LWR) fuels are fabricated from uranium which has been enriched in U-235. At a gaseous diffusion plant, natural uranium in the form of UF_6 is processed to increase the U-235 content from 0.7 percent up to 2 to 4 percent by weight. The enriched uranium hexafluoride product is shipped to LWR fuel fabrication plants where it is converted to solid uranium dioxide pellets and inserted into zirconium alloy (Zircaloy) tubes. The tubes are fabricated into fuel assemblies which are shipped to nuclear power plants. There are seven licensed uranium fuel fabrication facilities in the United States which fabricate commercial LWR fuel. Of the seven, only five had active operating licenses as of January 1, 1988. Of those five facilities, two use enriched uranium hexafluoride to produce completed fuel assemblies and two use uranium dioxide. The remaining facility converts UF_6 to UO_2 and recovers uranium from scrap materials generated in the various processes of the plant.

The processing technology used for uranium fuel fabrications consists of three basic operations: (1) chemical conversion of UF_6 to UO_2; (2) mechanical processing including

pellet production and fuel element fabrication; and (3) recovery of uranium from scrap and off-specification material. The most significant potential environmental impacts result from converting UF_6 to UO_2 and from the chemical operations involved in scrap recovery.

Non-LWR Fuel Fabrication Facilities

Only a few facilities produce the metal and mixed carbide fuel used in test and research reactors.

The non-oxide fuel fabrication process begins with highly enriched uranium metal. The uranium metal may be mixed with an alloying metal in an induction furnace. The fuel is then either rolled, punched, drilled, or crushed and compacted, and machined and shaped into the proper dimensions. Once the fuel is properly formed, it is enclosed in aluminum or stainless steel. The enclosing process may involve injection casting, loading into a can or mold, or simply covering the fuel with side plates and rolling the metals together. Finished fuel elements are then inspected and cleaned prior to assembly into fuel bundles.

The production of mixed carbide fuel starts with highly enriched uranium dioxide-thorium dioxide powder (UO_2-ThO_2). This powder is mixed with graphite and heated to form uranium-thorium carbide kernels. These kernels are formed into microspheres by heating to a temperature in excess of the kernels' melting point. The microspheres are then coated with carbon and silicon layers in a fluidized bed furnace. Fuel rods are formed by injecting the coated kernels and a matrix material into a hot mold. The finished rods are then inserted into a graphite block to form the final fuel assembly.

APPENDIX E

QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANTS AND FUEL REPROCESSING PLANTS

APPENDIX E

QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANTS AND FUEL REPROCESSING PLANTS

Quality assurance (QA) comprises all those planned and systematic actions necessary to provide confidence that a component will perform satisfactorily in service. Given the diversity of NRC-licensed facilities other than nuclear power reactors and the necessity to structure QA programs suited to the function of a facility, QA programs are themselves diverse, bearing closer resemblance to the highly structured power reactor programs as the complexity and risk potential of a facility increases.

QA programs must be documented by written policies, procedures, or instructions and must be carried out throughout the plant life. The QA program provides control over activities affecting the quality of components to an extent consistent with their importance to safety. The program must provide for the indoctrination and training of personnel performing activities affecting quality.

The QA criteria applicable to the power reactor program are listed below.[1] The purpose of each of the 18 QA criteria is briefly explained in the following pages. Some or all of the principles noted may apply in total or in part to NRC-licensed facilities other than nuclear power reactors. Refer to the individual paragraphs in the *Code of Federal Regulations* (10 CFR 30-39, 40, 50, and 70) for specific requirements.

Criterion 1 - Organization - To identify all activities affecting quality and to assure that the responsibilities and authorities of key personnel are clear.

Criterion 2 - Quality Assurance Program - To cause the project manager to articulate the actions necessary to plan and implement an effective quality assurance program.

Criterion 3 - Design Control - To control the following processes in accordance with the requirements of Applicable and Relevant or Appropriate Requirements: (1) designing tests and sampling patterns to characterize the geologic setting, to develop models to predict the

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[1] Appendix B to 10 CFR 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

performance and long-term stability of the site, and to predict the environmental interaction between the site and its surroundings; (2) specifying requirements for design and construction; and (3) designing computer codes.

Criterion 4 - Procurement Document Control - To provide the management controls to manage the work activities of contractors and subcontractors and ensure acceptable quality of the results.

Criterion 5 - Instructions, Procedures, and Drawings - To ensure the use of formal instructions for work activities related to the accomplishment of performance objectives and the design bases.

Criterion 6 - Document Control - To ensure that documents prescribing activities related to the accomplishment of the performance objectives and the design bases are controlled during review, approval, and distribution to ensure that those performing activities use approved and up-to-date instructions.

Criterion 7 - Control of Purchased Material, Equipment, and Services - To oversee and control the work of contractors and suppliers and to ensure that the results are consistent with performance objectives and design bases.

Criterion 8 - Identification and Control of Materials, Parts, and Components - To ensure that all materials, parts, samples, and components important to the accomplishment of performance objectives and the design bases are identified and controlled.

Criterion 9 - Control of Special Processes - To ensure that all work activities important to the accomplishment of performance objectives and the design bases are controlled, including the identification of activities that require specially trained personnel, or specialized equipment or procedures.

Criterion 10 - Inspection - To ensure that independent, pre-planned inspections are performed where it is deemed necessary to establish the acceptability of a product, process, or service, either in progress or upon completion.

Criterion 11 - Test Control - To ensure that tests are conducted to determine if an item or service is acceptable or to satisfy a need for more information.

Criterion 12 - Control of Measuring and Test Equipment - To ensure that measurements that affect quality of work are taken only with instruments, tools, gauges, or other measuring devices that are accurate, controlled, calibrated, and adjusted at predetermined intervals to maintain accuracy within necessary limits.

Criterion 13 - Handling, Storage, and Shipping - To ensure control over handling, storage, cleaning, packaging, preservation, and shipping of items affecting quality of work.

Criterion 14 - Inspection, Test, and Operating Status - To ensure the identification of the inspection and/or test status of samples, structures, systems, and components to prevent inadvertent use of items found to be unacceptable for use.

Criterion 15 - Nonconforming Materials, Parts, or Components - To ensure that items not conforming to specified requirements are identified and controlled to prevent inadvertent use.

Criterion 16 - Corrective Action - To ensure that management systems comprised by the QA program are constantly monitored and that timely measures are taken to correct conditions adverse to quality.

Criterion 17 - Quality Assurance Records - To ensure that records important to the accomplishment of performance objectives and the design bases (including the data analysis phase, hearings, permitting and licensing processes) are sufficient to demonstrate the quality of work performed. Records will also be needed should problems related to the performance of the facility occur at a later date.

Criterion 18 - Audits - To ensure that audits, which are part of the management system's sensors, are effective by being well planned, conducted by trained personnel familiar with the work being audited, and designed to measure the potential of the activity or process being audited to produce an acceptable product.

APPENDIX F

NRC AGREEMENT STATES AND STATE DIRECTORS

APPENDIX F

NRC AGREEMENT STATES AND STATE DIRECTORS*	
STATE	STATE DIRECTOR
1. Alabama	Mr. Aubrey V. Godwin, Chief Bureau of Radiological Health Environmental Health Administration Room 314, State Office Building Montgomery, Alabama 36130 (205)261-5313
2. Arizona	Mr. Charles F. Tedford, Director Radiation Regulatory Agency 4814 South 40th Street Phoenix, Arizona 85040 (602)255-4845
3. Arkansas	Ms. Greta Dicus, Director Division of Radiation Control and Emergency Management Department of Health 4815 West Markam Little Rock, Arkansas 72205-3867 (501)661-2301
4. California	Mr. Jack McGurk, Chief Environmental Health Branch State Department of Health 714/744 P Street, Room 498 Sacramento, California 95814 (916)332-2073 or 3482
5. Colorado	Mr. Robert Quillin, Director Radiation Control Division Office of Health Protection Department of Public Health 4210 East 11th Avenue Denver, Colorado 80220 (303)331-8480
6. Florida	Mary E. Clark, Ph.D., Director Office of Radiation Control Department of Health & Rehabilitative Services 1317 Winewood Blvd. Tallahassee, Florida 32399-0700 (904)487-1004

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7. Georgia	James L. Setser, Chief Environmental Protection Department of Natural Resources Floyd Towers East 1166 205 Butler Street Atlanta, Georgia 30309 (404)656-4713
8. Illinois	Thomas W. Ortcigar, Director Department of Nuclear Safety 1035 Outer Park Drive Springfield, Illinois 62704 (217)785-9868
9. Iowa	Donald A. Flater, Chief Bureau of Radiological Health Department of Public Health Lucas State Office Building Des Moines, Iowa 50319 (515)281-3478
10. Kansas	Mr. Gerald W. Allen, Chief X-Ray & Radioactive Materials Department of Health & Environment 109 S.W. 9th Street Topeka, Kansas 66620 (913)296-1562
11. Kentucky	Mr. John Volpe, Manager Radiation Control Branch Department of Health Services Cabinet for Human Resources 275 East Main Street Frankfort, Kentucky 40621 (502)564-3700
12. Louisiana	Mr. Glenn Miller, Administrator Radiation Protection Division Office of Air Quality & Nuclear Energy P.O. Box 82145 Baton Rouge, Louisiana 70884 (504)765-0160
13. Maryland	Mr. Roland G. Fletcher, Administrator Radiological Health Program Office of Toxics, Environmental Science and Health Department of the Environment 2500 Broening Highway Baltimore, Maryland 21224 (301)631-3300

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14. Mississippi	Mr. Eddie S. Fuente, Director Division of Radiological Health State Board of Health 3150 Lawson Street P.O. Box 1700 Jackson, Mississippi 39215-1700 (601)354-6657/6670
15. Nebraska	Mr. Harold Borchert, Director Division of Radiological Health State Department of Health 301 Centennial Mall South P.O. Box 95007 Lincoln, Nebraska 68509 (402)471-2168
16. Nevada	Mr. Stanley Marshall, Supervisor Radiological Health Section, Health Division Department of Human Resources 505 East King Street, Room 202 Carson City, Nevada 89710 (702)885-5394
17. New Hampshire	Ms. Diane Tefft, Program Manager Radiological Health Program Bureau of Environmental Health Division of Health Services Health & Welfare Building, Hazen Drive Concord, New Hampshire 03302 (603)271-4588
18. New Mexico	Benito J. Garcia, Chief Community Services Bureau Environmental Improvement Division Department of Health & Environment P.O. Box 968 Sante Fe, New Mexico 87504-0968 (505)827-2959
19. New York	Ms. Donna Ross, Energy Planner Division of Policy Analysis and Planning 2 Rockefeller Plaza Albany, New York 12223 (518)473-0048
20. North Carolina	Mr. Dayne H. Brown, Director Department of Environment, Health and Natural Resources Division of Radiation Protection P.O. Box 27687 Raleigh, North Carolina 27603 (919)741-4283

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21. North Dakota	Mr. Dana Mount, Director Division of Environmental Engineering Radiological Health Program State Department of Health 1200 Missouri Avenue Bismarck, North Dakota 58502 (701)221-5188
22. Oregon	Mr. Ray Paris, Manager Radiation Control Section Department of Human Resources 1400 South West Fifth Avenue Portland, Oregon 97201 (503)229-5797
23. Rhode Island	Shelly Robinson, Acting Chief Radioactive Materials & X-Ray Programs Department of Health Cannon Building, Davis Street Providence, Rhode Island 02908 (401)277-2438
24. South Carolina	Mr. Heyward G. Shealy, Chief Bureau of Radiological Health Department of Health and Environmental Control J. Marion Sims Building 2600 Bull Street Columbia, South Carolina 29201 (803)734-4700
25. Tennessee	Mr. Michael H. Mobley, Director Division of Radiological Health TERRA Building, 150 9th Avenue North Nashville, Tennessee 37219-5404 (615)741-7812
26. Texas	Mr. David K. Lacker, Chief Bureau of Radiation Control Department of Health 1100 W. 49th Street (mail only) Austin, Texas 78756 (512)835-7000
27. Utah	Mr. Larry Anderson, Director Bureau of Radiation Control State Department of Health 288 North 1460 West P.O. Box 16690 Salt Lake City, Utah 84116-0690 (801)538-6734

NRC AGREEMENT STATES AND STATE DIRECTORS*	
STATE	STATE DIRECTOR
28. Washington	Mr. Terry R. Strong, Director Office of Radiation Protection Department of Health Mail Stop LE-13 Olympia, Washington 98504 (206)586-8949

* As of August 1991

APPENDIX G

RANDOM SURVEY QUESTIONNAIRE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
AIR AND RADIATION

On October 31, 1989, the U.S. Environmental Protection Agency (EPA) promulgated standards controlling radionuclide air emissions from facilities licensed by the Nuclear Regulatory Commission, or certain agreement States. This regulation is under reconsideration and the Agency needs to gather information to determine whether or not these standards should be put into effect. The facilities being studied are licensed to handle or use radioactive materials in unsealed form. This facility has been selected to take part in a study to determine the radiation hazard to individuals residing outside the facility. Please fill out the enclosed form and return it within 30 days of the receipt of this request to:

Dale Hoffmeyer
U.S. Environmental Protection Agency
Mail Code ANR 460W
401 M Street, SW
Washington, DC 20460

This information is being requested under Section 114 of the Clean Air Act. Under Section 114 of the Act, the Administrator has the authority to require any person to submit information to assist EPA in developing National Emission Standards for Hazardous Air Pollutants under Section 112.

Please be advised that failure to provide all the information required by this Reporting Requirement within the time allowed, or to provide adequate written justification for such failure, can result in enforcement action by EPA against you under Section 113 of the Clean Air Act. Such enforcement may include a civil action for the assessment of monetary penalties. You should also be aware that Section 113 provides for possible criminal sanctions for anyone who knowingly makes any false statement, representation, or certification in a report required by EPA.

You may assert a business confidentiality claim covering part or all of the information responsive to this Reporting Requirement in the manner described in 40 C.F.R. Section 2.203(b). EPA will disclose information covered by such a claim only to the extent and according to the procedures set forth in 40 C.F.R. Part 2, Subpart B. If you do not submit a confidentiality claim with the information, EPA may disclose your response without further notice to you. You should read the above-cited regulations carefully before asserting a business confidentiality claim, since certain categories of information are not properly subject to such a claim.

If you have any questions concerning this letter or if you would like assistance in completing the form, call (800-685-3339) from 9 a.m. to 5 p.m. eastern standard time.

Sincerely,

William G. Rosenberg
Assistant Administrator
for Air and Radiation

Enclosure

SURVEY FORM

Facility Name_____
Address_____
City_____State_____Zip_____

Identify a person from whom clarification or additional information can be obtained, if necessary.

Name_____Telephone (___)_____

Does your facility handle only sealed radiation sources?

Sealed sources include "Special Form" sources that are sealed and not intended to be opened in their routine application; e.g., density and thickness gages.

Yes____ **STOP** You do not have to complete the remainder of this form. However, you must return the form to the EPA.

No_____ **CONTINUE** You must complete the remainder of this form.

Indicate the principal activities conducted at your facility which involve unsealed forms of radionuclides (check all that apply):

[ ] Accelerator
[ ] Research/Test Reactor
[ ] Nuclear Medicine (Diagnostic only)
[ ] Nuclear Medicine (Diagnostic and Therapeutic)
[ ] Manufacturer of Teletherapy Equipment
[ ] Manufacturer of Medical Implant Needles or Seeds
[ ] Manufacturer of Pacemakers
[ ] Manufacturer of Industrial/Scientific Gauging Equipment
[ ] Manufacturer of Self-Illuminating Devices
[ ] Producer of Radiopharmaceuticals
[ ] Producer of Radio-Labelled Compounds for Research
[ ] Producer of Munitions using Depleted Uranium
[ ] Producer of Shielding using Depleted Uranium
[ ] Thorium/Rare Earth Processing/Recovery
[ ] Low-Level Waste Disposal Facility
[ ] Low-Level Waste Incinerator
[ ] Low-Level Waste Transfer Agent (Prepackage only_____,re-package_____)
[ ] Research Laboratory (Indicate field of research_____)
[ ] Other (please specify_____)

GENERAL INSTRUCTIONS

1. **You must provide the information requested on pages 2-3 of this form <u>separately for each building</u> at your facility where radionuclides in unsealed form are handled.**

2. **If a question does not apply to your facility, then mark the appropriate space "N/A". If you cannot answer a question, mark the appropriate space "U".**

BUILDING NAME_____

Step 1. **Provide the approximate building dimensions in meters.**

Length_____ Width_____ Height_____

(if the building is irregularly shaped, the length and width should be those of the smallest rectangle that in plan view would completely encompass the building; the height should be the distance from the ground to the highest roof.)

Step 2. **Provide the following information for each stack/vent that serves an area in the building where unsealed forms of radioactive materials are handled.**

STACK/VENT	Height (m)[1]	Diameter (m)[2]	Flow Rate (m^3/sec)	Temperature (^oF)[3]	Effluent Controls (specify type)
1					
2					
3					
4					
5					

If there are more than 5 stacks/vents serving this building, check here____ and provide the information for the additional stacks/vents on a separate sheet of paper which clearly designates the building name.

[1]Distance from the ground to the top of the stack/vent.
[2]If the stack/vent is rectangular, give its length and width.
[3]If the exit temperature is approximately the same as the ambient temperature, simply enter an A for ambient.
NOTE: If the data you have is in units other than those requested and you are uncertain of the conversion, provide your data with the units clearly indicated; e.g. ft. for feet, CFM for ft^3/min, and ^oC for degrees celsius.

Step 3. **Does anyone live in this building?**

If YES, enter the distance along the building surface from the stack/vent to the nearest residence in the building _____(meters)

If NO, enter the distance from the stack/vent to the nearest residence outside the building. _____(meters) Indicate the direction from the stack/vent to the nearest residence. ____ (N,NNE,NE etc.)

Step 4. **Is there an office, school or business, not part of the facility covered by the NRC or state license, in this building?**

If YES, enter the distance along the building surface from the stack/vent to the nearest office, school or business. _____(meters)

If NO, enter the distance from the stack/vent to the nearest office, school or business outside the building. _____(meters) Indicate the direction from the stack/vent to the nearest office, school or business.___ (N,NNE,NE etc.)

Step 5. **Provide the distances in meters to the following sources of food production. If the distance is greater than 2000 meters, then enter >2000.**

Vegetables_____ Meat_____ Milk_____

Step 6. **Complete the table below.**

You must report all radionuclides in unsealed forms used in the building even if you do not believe that they are being released.

If you cannot provide the emission or quantity used information requested below for each stack/vent, then enter the values for the entire building under the column for stack 1.

MONITORED STACKS/VENTS

If you measure radionuclide emissions, enter the release rate for each radionuclide in Ci/y. Designate that it is a measured value by entering an M in the column headed "M/Q", and leave the column headed "Physical Form" blank. If radionuclide emissions are below the minimum detectable level, enter that level (Ci/y) preceded by a < symbol.

UNMONITORED STACKS/VENTS

If emissions of any radionuclides used are not measured, enter the quantity of each radionuclide used (Ci/y) but not measured and enter a Q in the column headed "M/Q". In the column headed "Physical Form", enter G for radionuclides that are gases or subject to temperatures in excess of 100°; L for radionuclides that are handled in liquid or powder forms; and S for radionuclides handled in solid forms or capsules. (Mo-99 contained in a generator to produce Technetium-99m can be assumed to be a solid.) If a radionuclide is used in more than one physical form, provide a separate entry for each.

Note: For both monitored or unmonitored emissions, if you know the lung clearance class for a radionuclide, enter it in the table. Use D for days, W for weeks, and Y for years. If the chemical species of a radionuclide falls into more than one clearance class, make a separate entry for each. If the lung clearance class is not known, enter the predominate chemical species if known.

Nuclide	M/Q	Physical form	Clearance class	Dates Covered: From _____ To _____				
				Stack 1 (Ci/Y)	Stack 2 (Ci/y)	Stack 3 (Ci/y)	Stack 4 (Ci/y)	Stack 5 (Ci/y)

If there is not enough space in the table to list all radionuclides used, check here____ and provide the information for the additional radionuclides on a separate sheet of paper which clearly designates the building name.

APPENDIX H

DOSE CALCULATION ASSUMPTIONS

This appendix provides details of calculational assumptions made regarding factors having a significant effect on dose.

Contents

Tables:

APPENDIX H

DOSE CALCULATION ASSUMPTIONS

H.1 ASSUMPTIONS RELATED TO SOURCE TERM

- Xe-133 Release from Hospitals

All the Xe-133 used by hospitals was assumed to be released. This assumption is appropriate for most hospitals but tends to overestimate the dose for others. While many hospitals trap the Xe-133 exhaled by the patients and allow it to decay for a number of half-lives, only a few of the hospitals surveyed indicated that they did so. Trapping the gas reduces the amount available to be released into the environment.

In order to properly account for Xe-133 trapping, it would have been necessary to contact each hospital to determine the details of its procedures. Because Xe-133 was the principal contributor to dose for many of the hospitals, a reduction in Xe-133 release would lower the median dose of the population. However, it would not have much effect on the doses above 1 mrem/yr as shown below:

Table H-1. Doses above 1 mrem/yr.

Facility	As Calculated	All Xe-133 Trapped
NH	1.1	1.1
NH	1.7	1.7
HN	1.8	1.8
H	2.0	0.9
H	3.9	0.6
NH	5.3	5.3
NH	8.0	8.0

NH = non-hospital, H = hospital, HN = hospital, no Xe

Twenty-three facilities have estimated doses above 0.1 mrem/yr. Of these 23, Xe-133 is a contributor in five. Of these five, the Xe-133 contribution to the total dose is 30, 40, 50, 80, and 85 percent, for an average of approximately 60 percent.

It is concluded that neglecting Xe-133 trapping by hospitals has a negligible effect upon the distribution of estimated doses.

- Release Fractions

For those facilities that did not provide site-specific release rates, the default release fraction of 1E-03, described in EPA89b, was used for liquids. As applied to nonvolatile radionuclides, such as Tc-99m or buffered solutions of radioiodine, this assumption will generally result in a higher estimate of the radionuclide release rate.

- Xe-133 Release from Radiopharmacies

EPA89b specifies a release fraction of 1.0 for radionuclides in gaseous form. However, because radiopharmacies receive and distribute the Xe-133 in sealed vials, very little is released. The Food and Drug Administration's limit on the leakage from these vials is 0.5 percent per day; however, in practice, the measured leakage is a maximum of 0.1 percent per day (Mu91).

The total leakage is a function of both the release rate (percent per day) and the length of time the vial is held in stock. Because Xe-133 has a half-life of only five days, it is unlikely that it would be held in stock for very long. If it were to be held for 10 days, the amount would have decayed to only one fourth the amount received by the radiopharmacy.

A 0.1 percent per day leakage rate and a holding time of 10 days was assumed. This results in a release fraction of one percent.

- Emissions from Sources Other Than Stacks and Vents

Radionuclide air emissions from stacks and vents were considered in this study, but emissions from diffuse sources were not covered. These include: fugitive emissions from normal operations (e.g., releases from patients treated with radionuclides); spilling and mishandling; and more catastrophic accidental releases such as fires and explosions. Exposures from these sources could make some of the annual doses actually received by members of the general public greater than those calculated in this study. However, the contribution of these sources to lifetime risks are generally believed to be low because the occurrences are usually infrequent and the exposures are for a short duration.

H.2 ASSUMPTIONS RELATED TO DISPERSION

- Closest Person Versus Maximally Exposed Person

In calculating the doses to the maximally exposed individual, the distance and direction to the closest office, school, or business were used. It is possible that an individual located at a greater distance, but in a sector toward which the wind blows more frequently, could receive a higher dose. However, should such a circumstance arise, the dose would be underestimated by no more than a factor of about 5.

The preceding discussion applies only to those cases in which a wind rose was used. If the closest person was on the same building, a wind rose was not used. For this reason, there is only a minimal effect on the doses above 1 mrem/yr as shown below.

Table H-2. Doses above 1 mrem/yr, no wind rose.

Facility	As Calculated	Person in Max Sector
NR	1.1	1.1
NR	1.7	1.7
RW	1.8	2.0
NR	2.0	2.0
NR	3.9	3.9
NR	5.3	5.3
NR	8.0	8.0

NR = no wind rose used (same building); RW = wind rose, near wake

Of the 23 facilities having doses greater than 0.1 mrem/yr, 15 have the closest residence, office, or classroom in the same building, five have them within the near-wake region, and three have them outside the near-wake region. The ratios of the maximum to the closest receptor for these are 1.0, 1.5, and 2.1, for an average of 1.5.

It is concluded that calculating the dose to the person in the closest residence, office or classroom, rather than in the location of maximum dose, had a negligible effect upon the distribution of doses.

- Same Building Effect

The estimate of the air concentration when the source and receptor are on the same building is quite conservative. The model used by COMPLY is based on NCRP Commentary No. 3. NRCP based its model on a study by Wilson and Britter (Wi82), which found that the concentration at various locations on a building was a function of the wind speed and the distance (measured along the building surface between the source and the receptor). The correlation is $C/Q = B/ux^2$, where C/Q is the normalized concentration, B a constant, u the wind speed, and x the distance between the source and the receptor.

Wilson and Britter suggest a value of 9 for B unless both the source and receptor are on the lower third of the same or adjacent walls, in which case they suggest a value of 30. The NCRP model uses 30 for all cases.

While the correlation based on these parameters seems reasonable, their data show a great deal of scatter. With B = 9, more than 90 percent of the data points lie above the correlating line. This means that their correlation encompasses more than 90 percent of the data points; it is not a mean line. The mean line lies about a factor of 5 above their line. That is, using the mean line would lead to B being about 1.4.

The NCRP method tends to overestimate dose. However, this has utility for regulatory purposes, as it means there is only a small chance that a facility might appear to be in compliance with the limit when the true concentration would result in a dose exceeding the limit.

H.3 ASSUMPTIONS RELATED TO THE RECEPTOR

- Age and Select Populations

Following the recommendations of the International Commission on Radiation Protection (ICRP80), this study assumed that doses were delivered to a standard man. In most cases, we have no information on the age or the predisposition of the exposed population which would lead us to conclude that either doses or risks would be greater than those estimated. However, for certain exposure groups considered in this study, such as students attending school, the average age may be less than that of standard man and the

annual dose may be greater than that calculated. The models used by EPA do not explicitly account for these factors, but since the cancer risks are assumed to result from a lifetime of exposure, underestimates associated with age at time of exposure would tend to be mitigated.

- Dose Conversion Factors

The dose conversion factor (DCF) is one of the key parameters used to calculate the doses associated with radionuclide emissions from facilities licensed under 10 CFR 30. The DCFs used in this report establish the relationship between a given intake of a radionuclide or concentration in the environment and the dose to a person exposed to the radionuclide. For radionuclides that are either inhaled or ingested, the DCF is expressed in units of the dose per unit activity inhaled or ingested. The values are isotope specific and are typically expressed in units of Sv/Bq[1] or mrem/Ci inhaled or ingested. For external exposures, the DCFs are expressed in units of dose rate per unit radionuclide concentration in the environment. For example, the DCFs for external exposure associated with immersion in a cloud of radioactivity are often expressed in units of mrem/yr per Ci/m^3. For external exposure from activity deposited on the ground, the DCF is typically expressed in units of mrem/yr per Ci/m^2.

DCFs are convenient values because, once the inhalation rate or ingestion rate of a given radionuclide is determined, the internal dose is readily obtained by multiplying by the appropriate DCF. Similarly, once the concentration of a given radionuclide in air or on the ground is determined, the external dose rate from immersion or direct radiation from standing on the contaminated ground is readily obtained by multiplying by the appropriate DCF.

Imbedded in the COMPLY code are default values for the DCFs for virtually all radionuclides for inhalation, ingestion, and external exposure. The purpose of this section is to explore the degree of conservatism, if any, inherent in these DCFs as used in this project. The discussion is divided into three parts: Inhalation DCFs, Airborne Immersion DCFs, and DCFs for External Exposure to Deposited Radionuclides. The discussions focus on the radionuclides, pathways, and facilities found to be the most significant on this project.

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[1] Sievert (Sv) is the international system unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems). One becquerel (Bq) is equal to 1 disintegration per second.

Inhalation DCFs. In the biomedical community, which represents the majority of the facilities addressed by this project, the principal radionuclides contributing to inhalation exposures are Tc-99m and I-131. The inhalation DCFs used by COMPLY are:

Tc-99m 3.26E+04 mrem/Ci or 8.80E-12 Sv/Bq inhaled
I-131 3.29E+07 mrem/Ci or 8.89E-09 Sv/Bq inhaled

These values were obtained from Table 2.1 of Federal Guidance Report No. 11, which is the EPA guidance regarding DCFs (EPA88). Inspection of Federal Guidance Report No. 11 reveals that these are committed effective dose equivalent factors (CEDE), which means that the doses obtained using these DCFs represent the whole body dose equivalent for the actual dose delivered to a specific organ. For example, exposure to I-131 results predominantly in a dose to the thyroid gland. However, the I-131 DCF includes a weighting factor, which converts the dose to the thyroid gland to the whole body dose that is equivalent, based on the effects of radioactive material in subsequent years following intake. In the case of thyroid exposure, the DCF includes a weighting factor of 0.03. The weighting factor for a tissue represents the proportion of stochastic risk resulting from irradiation of that tissue compared to the total risk when the whole body is uniformly irradiated. Therefore, as defined by ICRP, 3 percent of the total risk following whole body exposure is attributable to the exposure of the thyroid.

The DCFs in Federal Guidance Report No. 11 are 50-year dose commitments. This means, for a given intake of a radionuclide, the doses calculated using these DCFs are the effective doses for the 50-year period following intake. Imbedded in these values are assumptions regarding the clearance rate of the radionuclides from the body, which also bear on the realism of the DCFs.

The following presents a closer look at the inhalation DCFs for Tc-99m and I-131.

The Inhalation DCF for Tc-99m. The degree of conservatism inherent in the inhalation DCF for Tc-99m used on this project must be discussed from two perspectives. The first has to do with alternative DCFs provided in Federal Guidance Report No. 11 and the specific alternative selected for use on this project. The second has to do with conservatism inherent in the selected alternative.

Alternatives. Inspection of Federal Guidance Report No. 11 reveals that two different inhalation DCFs are provided for Tc-99m, 3.26E+04 and 2.67E+04 mrem/Ci inhaled. The former is referred to as the DCF for lung clearance class D (days) and the latter as the DCF for lung clearance class W (weeks) aerosols. Two different values are provided because the DCF differs depending on the clearance class of the Tc-99m. The D value is to be used for those forms of Tc-99m that are cleared from the lung relatively quickly, on the order of days. The W value is to be used for those forms of Tc-99m that are cleared from the lung more slowly, on the order of weeks. In COMPLY, the higher value was selected. As discussed in the following, the higher DCF is the more appropriate value to use for the chemical forms of Tc-99m used by the biomedical community.

Inspection of Federal Guidance Report No. 11 and ICRP 30 reveals that the inhalation DCF for Tc-99m is based on an assumed aerosol size distribution of 1 micron activity median aerodynamic diameter (AMAD) and a GI absorption fraction of 0.8, and that the Tc-99m is in the pertechnetate form. The assumption that the aerosol is 1.0 μm AMAD does not significantly affect the DCF because the DCF is based primarily on deposition and retention of transportable technetium. The GI absorption fraction of 0.8 is conservative as applied to many of the forms of Tc-99m that are not soluble, such as sulphur-colloid, but appropriate for the pertechnetate form. As discussed below, since the pertechnetate form is the most commonly used, this is a reasonable assumption. Finally, in developing the metabolic models for Tc-99m, a broad range of different forms of Tc-99m was considered. It was assumed that for both the W and D forms of inhaled Tc-99m, once absorbed, the retention of Tc-99m will follow that of the pertechnetate form. Of the various forms of Tc-99m, the dose equivalent for the pertechnetate form is generally higher than that of the other forms (ICRP87). In addition, it is the most widely used form of Tc-99m.

Inhalation DCF for I-131. The effective whole body DCF for the inhalation of I-131 is 3.29E+07 mrem/Ci. The value is based on the assumption that 100 percent of the inhaled iodine is absorbed (i.e., f1 = 1), 30 percent goes to the thyroid gland (i.e., f2 = 0.3), and the remainder is immediately excreted in the urine. The portion that goes to the thyroid gland is assumed to have an effective half-life of 7.5 days. These values are best estimates based on extensive experience with I-131. The f1 value of 100 percent is appropriate because the iodine is easily absorbed. The f2 value of 0.3 is consistent with, though somewhat more conservative than, the normal range of 0.05 to 0.25 referred to in ICRP90. The effective half-life of 7.5 days is determined almost entirely by the 8.04-day radiological half-life of I-131 and is therefore highly reliable.

Overall, the parameters used to calculate the thyroid dose to the typical adult from the inhalation of I-131 are realistic. However, the effective whole body DCF does have an inherent degree of conservatism of about 2 up to 15 fold. The conservatism stems from the way the thyroid DCF is converted to an effective whole body DCF.

As discussed above, the thyroid DCF is converted into an effective whole body DCF by multiplying the thyroid DCF by 0.03. The 0.03 value represents the relative radiotoxicity of a given dose of penetrating radiation to the thyroid gland as compared to the same dose given to the whole body. The weighting factor of 0.03 was based on data that found that for a given dose of external whole body radiation, approximately 0.03 of the cancer fatalities caused by the radiation were due to thyroid cancer. Accordingly, an external dose delivered to the thyroid gland alone is 0.03 as potentially harmful as the same dose delivered to the whole body.

The 0.03 weighting factor is appropriate for external exposures. However, there is evidence that the same dose of radiation delivered internally to the thyroid gland from I-131 can be a factor of from 2 to as high as 15 less radiocarcinogenic (NAS90) (NRC85c). This may be because a great majority of the dose to the thyroid gland from I-131 is due to beta particles, which deposit a large portion of their energy harmlessly in the colloid contained within the follicles of the thyroid gland. Others disagree, finding I-131 and x-rays equivalent in inducing thyroid cancer. In any case, the effective whole body DCF for I-131 may be conservative by a factor of 2 to 15.

External Immersion DCF. The external dose from immersion in Xe-133, Tc-99m, and I-131 is an important contributor to the offsite doses associated with routine emissions from hospitals and other materials licensees. COMPLY uses the external DCFs recommended by EPA in Table 2.3 of Federal Guidance Report No. 11 and in a DOE publication (DOE88). These DCFs are based on the assumption that the individual is immersed in a semi-infinite cloud. In the real world, the cloud is of finite dimensions; the assumption of a semi-infinite cloud could significantly overestimate the dose. The degree of conservatism in the DCF depends on the size of the cloud and the energy of the photon emitted by the radionuclide. For example, for a typical 0.7 MeV gamma emitter, a plume of about 1000 meters will act as an effectively semi-infinite cloud. However, the dose from a plume of 100 meters will be about 1/2 the semi-infinite cloud dose, and the dose from a plume of about 10 meters in diameter, will deliver a dose 1/10 the semi-infinite cloud dose

(DOE84). For receptors close to the source, where the dimensions of the plume are relatively small, the assumption of a semi-infinite cloud will likely introduce at least a two-fold conservatism.

External DCF from Standing on Contaminated Ground. The external dose from standing on ground contaminated with Tc-99m and I-131 is another important contributor to the offsite doses associated with routine emissions from hospitals and other materials licensees. COMPLY uses the external DCFs recommended in DOE publications (DOE88). These DCFs are based on the assumption that the individual is standing on an infinite, smooth plane. In reality, the contaminated area is of a finite dimension and the ground is generally not smooth. As a result, the doses derived using DCFs based on an infinite smooth plane may overestimate the dose by at least a factor of 2.

H.4 REFERENCES

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ICRP80 International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP 30, August 1980.

ICRP87 International Commission on Radiological Protection, "Protection of the Patient in Nuclear Medicine," ICRP 52, 1987.

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Mu91 Mullins, T. J., DuPont/Merck, letter to S. Beal, December 1991.

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Wi82 Wilson, D. J., and Britter, R. E., "Estimates of Building Surface Concentrations from Nearby Point Sources," Atmospheric Environment, 16, 2631, 1982.